# Appendix B: Fatty Acids, Tall Oil, Cobalt Salts

Prepared by the Metal Carboxylates Coalition



## 1.0 SUBSTANCE INFORMATION

| | | |
|---|---|---|
| **Generic Name** | : | Fatty acids, tall oil, cobalt salts |
| **Chemical Name** | : | Fatty acids, tall oil, cobalt salts |
| **CAS Registry No.** | : | 61789-52-4 |
| **Component CAS Nos.** | : | |
| **EINECS No.** | : | |
| **Structural Formula** | : | |
| **Molecular Weight** | : | |
| **Synonyms and Tradenames** | : | Cobalt tallate;<br>Tall oil fatty acids, cobalt salts |
| **References** | : | |

### 2.1 MELTING POINT

| | | |
|---|---|---|
| **Type** | : | Melting Point/Melting Range Determination |
| **Guideline/method** | : | OECD 102; EPA OPPTS 830.7200 |
| **Value** | : | -38 to -39°C |
| **Decomposition** | : | at °C |
| **Sublimation** | : | |
| **Year** | : | 2003 |
| **GLP** | : | Yes |
| **Test substance** | : | Fatty acids, tall oil, cobalt salts, Lab batch 1022-49, 8.85% cobalt, very tacky red-purple solid, provided by OMG Americas |
| **Method** | : | OECD 102, Melting Point/Melting Range, July 1995; EPA Product Properties Test Guidelines, OPPTS 830.7200, Melting Point/Melting Range, March 1998 |
| **Method detail** | : | The freezing point, defined as the temperature at which phase transition from liquid to solid state at normal atmospheric temperature occurs, corresponds to the melting point. To determine the freezing point, 5 mL of test material was preheated in a waterbath at about 80ºC and then cooled using acetone and dry ice until solidification. A thermocouple probe in the center of the sample was used to measure temperature over time; the physical state was observed as well. The test was run in duplicate. |
| **Result** | : | The freezing point (melting point) was determined to be between -38ºC and -39ºC (equal to 234 – 235 K) |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Metal**: The melting point reported for cobalt chloride is 735ºC (Appendix C). |
| **Reliability** | : | [1] Reliable without restriction |
| **Reference** | : | Tognucci, A., 2003. Determination of the Melting Point/Melting Range of Fatty Acids, Tall Oil, Cobalt Salts, RCC Study No. 849114, conducted for the Metal Carboxylates Coalition by RCC Ltd., Switzerland. |

### 2.2 BOILING POINT

| | | |
|---|---|---|
| **Type** | : | Boiling Point/Boiling Range Determination |
| **Guideline/method** | : | OECD 103; EPA OPPTS 830.7220 |
| **Value** | : | Boiling point was not observed |
| **Decomposition** | : | |
| **Year** | : | 2003 |
| **GLP** | : | Yes |
| **Test substance** | : | Fatty acids, tall oil, cobalt salts, Lab batch 1022-49, 8.85% cobalt, very tacky red-purple solid, provided by OMG Americas |
| **Method** | : | OECD 103, Boiling Point, 1995; EPA Product Properties Test Guidelines, OPPTS 830.7220, Boiling Point/Boiling Range, August 1996 |
| **Method detail** | : | A differential scanning colorimeter (DSC 821, Fa, Mettler Toledo) was used to determine the boiling point/range (the temperature or temperature range at which the vapor pressure of a liquid is the same as the standard pressure). A preliminary test was conducted at a heating rate of 20 K/min from 25ºC to 400ºC and the quantities of heat absorbed or released were measured and recorded. The weight and appearance of the sample were recorded before and after the test. A definitive run was made at a heating rate of 10 K/min; however no peak was observed from which boiling could be deduced. |
| **Result** | : | The boiling point was not observed. |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Acid**: For tall oil fatty acids, the boiling point is reported as approx. 160 - 210 °C at 6.6 hPa. Union Camp Chemicals (Durham. UK); cited in year 2000 IUCLID dataset. |

| | | |
|---|---|---|
| | | **Metal:** The reported boiling point for cobalt chloride is 1,049ºC (Appendix C). |
| **Reliability** | : | [1] Reliable without restriction |
| **Reference** | : | Tognucci, A., 2003. Determination of the Boiling Point/Boiling Range of Fatty Acids, Tall Oil, Cobalt Salts, RCC Study No. 849115, conducted for the Metal Carboxylates Coalition by RCC Ltd., Switzerland. |

### 2.3 DENSITY

| | | |
|---|---|---|
| **Type** | : | Specific gravity |
| **Guideline/method** | : | |
| **Value** | : | 1.02 at 25°C |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Metal**: Reported value for cobalt chloride is 3.367 at 25ºC (Appendix C). |
| **Reliability** | : | |
| **Reference** | | Material Safety Data Sheet for cobalt tallate, OMG Americas, Inc. |

### 2.4 VAPOR PRESSURE

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Value** | : | hPa at °C |
| **Decomposition** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Acid:** For tall oil fatty acids, the vapor pressure is negligible at 25°C. Union Camp Chemicals (Durham. UK); cited in year 2000 IUCLID dataset. |
| **Reliability** | : | |
| **Reference** | : | |

### 2.5 PARTITION COEFFICIENT

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Partition coefficient** | : | |
| **Log Pow** | : | at °C |
| **pH value** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | Determination of octanol/water partition coefficient (Kow) is inappropriate for metal carboxylate compounds such as fatty acids, tall oil, cobalt salts. Kow is determined on unionized, undissociated chemicals. Due to the complex |

water chemistry of fatty acids, tall oil, cobalt salts, and the presence of dissociated ionized constituents, measuring Kow would be extremely difficult if not impossible, and would not provide meaningful data.
**Supporting data for dissociation products:**
**Acid:** When tested according to OECD Test Method 117, at pH 2, the log $P_{ow}$ values for seven compounds in tall oil fatty acid were 4.4, 7.0, 7.3, 7.5, 7.7, 8.0, and 8.3. At pH 7.5, the log $P_{ow}$ values for six compounds in tall oil fatty acid were 3.6, 3.8, 4.2, 4.5, 4.7, and 7.4. (Dybdahl, H.P. 1993). See robust summary prepared by the Pine Chemicals Association (Appendix E).
**Metal:** not applicable (ionizes in water).

**Reliability** :
**Reference** :

### 2.6.1 SOLUBILITY IN WATER

| | | |
|---|---|---|
| **Type** | : | Water Solubility Determination |
| **Guideline/method** | : | OECD 105; EPA OPPTS 830.7840 |
| **Value** | : | 149 mg/L at 20°C |
| **pH value** | : | |
| **concentration** | : | at °C |
| **Temperature effects** | : | |
| **Examine different pol.** | : | |
| **PKa** | : | at °C |
| **Description** | : | |
| **Stable** | : | |
| **Deg. product** | : | |
| **Year** | : | 2003 |
| **GLP** | : | Yes |
| **Test substance** | : | Fatty acids, tall oil, cobalt salts, Lab Batch 1022-49, 8.85% cobalt, very tacky red-purple solid, provided by OMG Americas |
| **Deg. products CAS#** | : | |
| **Method** | : | OECD 105, Water Solubility, 1995; EPA Product Properties Test Guidelines, OPPTS 830.7840, Water Solubility: Column Elution Method, Shake Flask Method, 1998. |
| **Method detail** | : | The results of a preliminary test using a simplified flask method indicated the solubility was below 10 mg/L; therefore, the column elution method was used in the definitive test. The column was prepared by adding 6.09 g of glass beads into a flask, adding 0.12 g of test material dissolved in 5 mL dichloromethane, and evaporating the solvent under a stream of nitrogen. This was then poured into the elution column which was subsequently filled with water and equilibrated for approximately 2 hours. A circulation pump was used to elute the test material from the carrier material. Temperature was 20ºC. The flow rate was 0.52 mL/min for 120 hours, followed by a period of 23 hours at 0.26 mL/min. The apparatus was run until equilibration of the saturation column was obtained, defined by at least five successive samples whose concentrations do not differ more than 30%. The column eluate was sampled at 1 hour intervals to determine the concentration of cobalt, using atomic absorption spectroscopy. |
| **Result** | : | Based on the results of 12 samples, the cobalt solubility was 13.2 mg Co/L (SD ± 2.8 mg/L) which corresponds to a water solubility of fatty acids, tall oil, cobalt salts of 149 mg FA Tall Oil Co Salt/L (calculated based upon cobalt content of 8.85% w/w). The pH during the test ranged from 5.59 to 5.62. |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Acid**: The water solubility of tall oil fatty acid, in its entirety as a complex mixture, was reported as 12.6 mg/L (Dinwoodie, N.B., 2003; see robust summary prepared by the Pine Chemicals Association in Appendix E). |

**Metal:** The reported water solubility for cobalt chloride is 450 g/L at 7ºC (Appendix C).

**Reliability** : [1] Reliable without restriction

**Reference** : Tognucci, A., 2003. Determination of the Water Solubility of Fatty Acids, Tall Oil, Cobalt Salts, RCC Study No. 849117, conducted for the Metal Carboxylates Coalition by RCC Ltd., Switzerland.

## 2.7 FLASH POINT

**Type** :
**Guideline/method** :
**Value** : °C
**Year** :
**GLP** :
**Test substance** :
**Method** :
**Method detail** :
**Result** :
**Remark** :
**Reliability** :
**Reference** :

### 3.1.1 PHOTODEGRADATION

| | | |
|---|---|---|
| **Type** | | |
| **Guideline/method** | : | |
| **Light source** | : | |
| **Light spectrum** | : | |
| **Relative intensity** | : | based on |
| **Spectrum of substance** | : | lambda (max, >295nm) : |
| | | epsilon (max) : |
| | | epsilon (295) : |
| **Conc. of substance** | : | at °C |
| **DIRECT PHOTOLYSIS** | | |
| **Halflife (t1/2)** | : | |
| **Degradation** | : | % after |
| **Quantum yield** | : | |
| **INDIRECT PHOTOLYSIS** | | |
| **Sensitizer** | : | |
| **Conc. of sensitizer** | : | |
| **Rate constant** | : | |
| **Degradation** | : | |
| **Deg. product** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Deg. products CAS#** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Acid**: AOPWIN v.191 was used to calculate photodegradation for two major components of fatty acids, tall oil. The half-life for oleic acid was 1-2 hours and the half-life for linoleic acid was 0.7 -1 hours.<br>**Metal:** not applicable, metal does not degrade. |
| **Reliability** | : | (1) Reliable without restriction |
| **Reference** | : | |

### 3.1.2 DISSOCIATION

| | | |
|---|---|---|
| **Type** | : | Dissociation constant determination |
| **Guideline/method** | : | OECD 112 |
| **pKa** | : | 5.82 at 20°C |
| **Year** | : | 2002 |
| **GLP** | : | Yes |
| **Test substance** | : | Cobalt tallate, CAS number 61789-52-4, received from OMG. Dark solid, purity of 20.6% cobalt |
| **Approximate water solubility** | : | 3.5 mg/L, determined by Inductively Coupled Plasma Atomic Emission Spectrometry during preliminary study |
| **Method** | : | OECD Guideline 112, Dissociation Constants in Water |
| **Method detail** | : | Three replicate samples of cobalt tallate were prepared at a nominal concentration of 1.5 mg/L by fortification of 100 mL of degassed water (ASTM Type II) with a 1.0 mg/mL stock solution of the test substance in methanol. Each sample was titrated against 0.00025 N sodium hydroxide while maintained at a test temperature of 20±1°C. At least 10 incremental additions were made before the equivalence point and the titration was carried past the equivalence point. Values of pK were calculated for a minimum of 10 points on the titration curve. Phosphoric acid and 4-nitrophenol were used as reference substances. |

| | | |
|---|---|---|
| **Result** | : | Mean (N = 3) pKa value was 5.82 (SD = 0.108) at 20°C |
| **Remark** | : | The results indicate that dissociation of the test substance will occur at environmentally-relevant pH values (approximately neutral) and at physiologically-relevant pH values (approximately 1.2). |
| **Reliability** | : | [1] Reliable without restriction. |
| **Reference** | | Lezotte, F.J. and W.B. Nixon, 2002. Determination of the dissociation constant of tall oil, cobalt salts, Wildlife International, Ltd. Study No. 534C-117, conducted for the Metal Carboxylates Coalition. |

### 3.2.1 MONITORING DATA

| | | |
|---|---|---|
| **Type of measurement** | : | |
| **Media** | : | |
| **Concentration** | : | |
| **Substance measured** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | |
| **Reliability** | : | |
| **Reference** | : | |

### 3.3.1 TRANSPORT (FUGACITY)

| | | |
|---|---|---|
| **Type** | : | |
| **Media** | : | |
| **Air** | : | % (Fugacity Model Level I) |
| **Water** | : | % (Fugacity Model Level I) |
| **Soil** | : | % (Fugacity Model Level I) |
| **Biota** | : | % (Fugacity Model Level II/III) |
| **Soil** | : | % (Fugacity Model Level II/III) |
| **Year** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Acid**: EPIWIN v3.11 was used to determine fugacity (Level III) for two major components of fatty acids, tall oil. Results are: |

| | Mass amount (%) | Half-life (hr) | Emissions (kg/hr) |
|---|---|---|---|
| Oleic acid | | | |
| Air | 0.0999 | 1.3 | 1000 |
| Water | 7.49 | 360 | 1000 |
| Soil | 28.1 | 360 | 1000 |
| Sediment | 64.3 | 1440 | 0 |
| Persistence time: 616 hr | | | |
| Linoleic acid | | | |
| Air | 0.0546 | 0.691 | 1000 |
| Water | 8.07 | 360 | 1000 |
| Soil | 28.7 | 360 | 1000 |
| Sediment | 63.1 | 1440 | 0 |
| Persistence time: 603 hr | | | |

| | | |
|---|---|---|
| **Reliability** | : | (1) Reliable without restriction |
| **Reference** | : | |

### 3.5 BIODEGRADATION

| | | |
|---|---|---|
| **Type** | : | Read across from Co stearate |
| **Guideline/method** | : | |
| **Inoculum** | : | |
| **Concentration** | : | related to<br>related to |
| **Contact time** | : | |
| **Degradation** | : | (±) % after day(s) |
| **Result** | : | |
| **Kinetic of test subst.** | : | % (specify time and % degradation)<br>%<br>%<br>% |
| **Control substance** | : | |
| **Kinetic** | : | %<br>% |
| **Deg. product** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Deg. products CAS#** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Acid:** The biodegradability of tall oil fatty acids has been studied in several different tests. In a ready biodegradability closed bottle test (OECD 301D), the test material degraded 50% in 7 days and 56% in 28 days (Madsen, 1993). In a manometric respiratory test (OECD 301 F), the substance degraded 84% in 28 days (Aniol, 1999). In a ready biodegradability modified Sturm test (OPPTS 853.110), 74% of the test article degraded in 28 days (Sewell, 1994). See robust summaries prepared by the Pine Chemicals Association (Appendix E).<br>**Metal:** not applicable, metal does not degrade. |
| **Reliability** | : | |
| **Reference** | : | |

### 3.7 BIOCONCENTRATION

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Species** | : | |
| **Exposure period** | : | at °C |
| **Concentration** | : | |
| **BCF** | : | |
| **Elimination** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | |
| **Reliability** | : | |
| **Reference** | : | |

## 4.1 ACUTE TOXICITY TO FISH

| | | |
|---|---|---|
| **Type** | : | Read across from Co stearate |
| **Guideline/method** | : | |
| **Species** | : | |
| **Exposure period** | : | |
| **NOEC** | : | |
| **LC0** | : | |
| **LC50** | : | |
| **LC100** | : | |
| **Other** | : | |
| **Other** | : | |
| **Other** | : | |
| **Limit test** | : | |
| **Analytical monitoring** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Acid:** In a study conducted according to OECD 203, fathead minnows (*Pimephales promelas*) were exposed to water accommodated fractions of tall oil fatty acid. The 96-h LL50 was > 1000 mg/L, which was the highest loading rate tested. The NOEL was 1000 mg/L. (Kelly, 2002. See robust summary prepared by the Pine Chemicals Association (Appendix E).<br>The 96-h LC50 for zebrafish is reported to be 10 to 20 mg/L for tall oil fatty acids. Arizona Chemical Company letter to U.S EPA dated November 2, 1999. [Available from the National Technical Information Service in microfiche OTS0559827, Initial submission letter from attorneys of Arizona Chemical Co. to USEPA regarding 17 health and ecotoxicity studies of various chemicals with attachments and dated 110299 (sanitized)].<br>**Metal:** For cobalt chloride, the 96-h LC50 was 1.41 mg Co/L for the highly sensitive rainbow trout, *Onchorynchus mykiss.* Toxicity to other fish species ranges from LC50 values of 22 – 333 mg Co/L. Toxicity is dependent upon water hardness (Appendix C). |
| **Reliability** | : | |
| **Reference** | : | |

## 4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

| | | |
|---|---|---|
| **Type** | : | Acute *Daphnia* |
| **Guideline/method** | : | OECD #202 |
| **Species** | : | *Daphnia magna* |
| **Exposure period** | : | 48 h |
| **NOEC** | : | |
| **EC0** | : | |
| **EC50** | : | 8.8 mg cobalt tallate/L (0.77 mg Co/L) |
| **EC100** | : | |
| **Other** | : | |
| **Other** | : | |
| **Other** | : | |
| **Limit test** | : | |

| | | |
|---|---|---|
| **Analytical monitoring** | : | Nominal: 6.3, 13, 25, 50 and 100 mg cobalt tallate/L (equivalent to 0.56, 1.1, 2.2, 4.5 and 8.9 mg Co/L); Measured: 0.76, 2.0, 3.1, 7.3 and 15 mg cobalt tallate/L (equivalent to 0.067, 0.18, 0.28, 0.65 and 1.3 mg Co/L) |
| **Year** | : | 2007 |
| **GLP** | : | yes |
| **Test substance** | : | Fatty acids, tall-oil cobalt salt, Batch No. 1059-50 (LB1059-50), CAS No. 61789-52-4, reported to have a purity of 8.91% as cobalt (tested as 100%) was received from OMG Americas, Westlake, Ohio on 23 May 2006. |
| **Method** | : | OECD #202 |
| **Method detail** | : | |
| **Result** | : | The 48-hour EC50 value for cobalt tallate and Daphnia magna was determined by probit analysis to be 8.8 mg cobalt tallate/L (0.77 mg Co/L) with 95% confidence intervals of 6.5 to 13 cobalt tallate/L (0.58 to 1.1 mg Co/L). The No-Observed-Effect Concentration (NOEC) was determined to be 2.0 mg cobalt tallate/L (0.18 mg Co/L). |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Acid:** In a study conducted according to OECD 202, Part 1, *Daphnia magna* were exposed to water accommodated fractions of tall oil fatty acid. The 48-h EL50 was > 1000 mg/L, which was the highest loading rate tested. The NOEL was 1000 mg/L. (Kelly, 2002. See robust summary in attached document prepared by the Pine Chemicals Association (Appendix E).<br>The 48-h EC50 for *Daphnia magna* is reported as 55.7 mg/L for tall oil fatty acids. Arizona Chemical Company letter to U.S EPA dated November 2, 1999. [Available from the National Technical Information Service in microfiche OTS0559827, Initial submission letter from attorneys of Arizona Chemical Co. to USEPA regarding 17 health and ecotoxicity studies of various chemicals with attachments and dated 110299 (sanitized)].<br>**Metal:** For cobalt chloride, the 48-h EC50 value for *Daphnia magna* was 1.52 mg Co/L. In other studies, and with other species, 48-h LC50 values ranged from 1.52 – 5.5 mg Co/L (Appendix C). |
| **Reliability** | : | [1] without restriction |
| **Reference** | : | Fatty Acids, Tall-Oil, Cobalt Salt - Acute Toxicity to Water Fleas, (*Daphnia magna*) Under Flow-through Conditions (2007). Conducted by Springborn Smithers Laboratories for the Metal Carboxylates Coalition. Study No. 13865.6115 |

### 4.3 TOXICITY TO AQUATIC PLANTS (E.G., ALGAE)

| | | |
|---|---|---|
| **Type** | : | Read across from Co stearate |
| **Guideline/method** | : | |
| **Species** | : | |
| **Endpoint** | : | |
| **Exposure period** | : | |
| **NOEC** | : | |
| **LOEC** | : | |

| | | |
|---|---|---|
| **EC0** | : | |
| **EC10** | : | |
| **EC50** | : | |
| **Other** | : | |
| **Other** | : | |
| **Other** | : | |
| **Limit test** | : | |
| **Analytical monitoring** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Acid:** In a study conducted according to OECD 201, the green alga *Selenastrum capricornutum* was exposed to water accommodated fractions of tall oil fatty acid. The 72-h EL50 based on area under the growth curve was 854 mg/L with a corresponding NOEL of 500 mg/L. The 72-h EL50 based on average specific growth rate was > 1000 mg/L with a corresponding NOEL of 750 mg/L. (Kelly, 2002. See robust summary in attached document prepared by the Pine Chemicals Association (Appendix E).<br>The growth inhibition EC50 values for three algal species were reported to range from 0.79 to 9 mg/L for tall oil fatty acids. Arizona Chemical Company letter to U.S EPA dated November 2, 1999. [Available from the National Technical Information Service in microfiche OTS0559827, Initial submission letter from attorneys of Arizona Chemical Co. to USEPA regarding 17 health and ecotoxicity studies of various chemicals with attachments and dated 110299 (sanitized)].<br>**Metal:** For cobalt chloride, the 96-h EC50 for *Chorella vulgaris* was 0.52 mg Co/L. Other aquatic plant species were less sensitive, with EC50 values from 16.9 – 23.8 mg Co/L (Appendix C). |
| **Reliability** | : | |
| **Reference** | : | |

## 5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

| | | |
|---|---|---|
| **In vitro/in vivo** | : | |
| **Type** | : | |
| **Guideline/method** | : | |
| **Species** | : | |
| **Number of animals** | : | |
| **Males** | : | |
| **Females** | : | |
| **Doses** | : | |
| **Males** | : | |
| **Females** | : | |
| **Vehicle** | : | |
| **Route of administration** | : | |
| **Exposure time** | : | |
| **Product type guidance** | : | |
| **Decision on results on acute tox. tests** | : | |
| **Adverse effects on prolonged exposure** | : | |
| **Half-lives** | : | 1st:<br>2nd:<br>3rd: |
| **Toxic behavior** | : | |
| **Deg. product** | : | |
| **Deg. products CAS#** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Metal:** Absorption of cobalt in the digestive tract is influenced by the chemical form of the metal, with increasing solubility resulting in increased adsorption. Approximately 13-34% of cobalt chloride, a soluble form, is absorbed in the gut of rats, but absorption in the gut may be increased in iron deficient individuals. Following oral exposure, cobalt is eliminated primarily in feces and secondarily in urine. For the more soluble forms of cobalt, e.g., cobalt chloride, 70 – 80% of the administered dose is eliminated in the feces. For absorbed cobalt, elimination is rapid primarily in the urine (Barceloux, D.G. (1999) Cobalt. Clin. Tox. 37(2):201-206). Elimination is biphasic or triphasic. The terminal phase involves a very small residual level of cobalt and has a half-life in years (Appendix C). |
| **Reliability** | : | |
| **Reference** | : | |

### 5.1.1 ACUTE ORAL TOXICITY

| | | |
|---|---|---|
| **Type** | : | Acute Oral Toxicity Study in Rats – Up and Down Procedure |
| **Guideline/Method** | : | OECD #425 |
| **Species** | : | Rats |
| **Strain** | : | Crl:CD(SD) |
| **Sex** | : | Female |
| **Number of animals** | : | 7 |
| **Vehicle** | : | Corn oil |

| | | |
|---|---|---|
| **Doses** | : | 2000, 550, and 175 mg/kg |
| **LD50** | : | 2000 mg/kg females |
| **Year** | : | 2007 |
| **GLP** | : | Yes |
| **Test substance** | : | The test substance, cobalt tallate, was supplied by the sponsor. The test substance appeared to be stable under the conditions of the study. No evidence of instability, such as a change in color or physical state, was observed. The water solubility was estimated to be 149 mg/L at 20□C and the equilibrium constant is reported as pKa was 5.82 at 20□C. |
| **Method** | : | OECD, Section 4 (Part 425): Acute Oral Toxicity - Up-and-Down Procedure, Guideline for the Testing of Chemicals (2001) |
| **Method detail** | : | |
| **Result** | : | The oral $LD_{50}$ for cobalt tallate was 2000 mg/kg for female rats. Body weight loss of approximately 13% of the fasted weight occurred by day 7 in one of the rats dosed at 2000 mg/kg. No other biologically important weight losses occurred after dosing. There were no test substance-related gross lesions found in the study. The only gross lesion observed, skin stain in rat 5902, was non-specific and not indicative of target organ toxicity. Clinical signs of toxicity were observed in all rats and included high or low carriage, ataxia, brown discharge from the vulva, wet fur, diarrhea, various staining, lethargy, red discharge from the anus, decreased muscle tone, paleness, and/or hair loss. With the exception of hair loss and staining, no clinical signs were observed after test day 10. |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Acid:** The acute oral LD50 of tall oil fatty acids has been reported as >10,000 mg/kg in rats using a test procedure consistent with OECD Test Method 401. (Mallory, 1983). See robust summary in attached document prepared by the Pine Chemicals Association (Appendix E).<br>**Metal:** Reported LD50s of cobalt chloride to rats range from 42.4 to 190 mg $CoCl_2$/kg bw (equivalent to 19.1 to 85.5 mg Co/mg bw). Toxicity of cobalt sulfate is reported to be similar to the chloride with oral LD50s for rats ranging from 123 to 161 mg/kg bw (equivalent to 46.7 to 61.2 mg Co/kg bw). For the mouse, LD50 values were reported as 89.3 and 123 mg/kg for cobalt chloride and the cobalt sulfate, respectively, which are equivalent to 40.2 and 56.7 mg/kg bw when expressed as cobalt (ATSDR Sept 2001 Draft; see Appendix C) |
| **Reliability** | : | [1] without restriction |
| **Reference** | : | Fatty Acids, Tall-oil, Cobalt Salt: Acute Oral Toxicity Study in Rats - Up-and-Down Procedure (2007) Conducted by DuPonts Haskell Laboratories for the Metal Carboxylates Coalition. Study No. 16641 |

### 5.1.2 ACUTE INHALATION TOXICITY

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Species** | : | |
| **Strain** | : | |
| **Sex** | : | |
| **Number of animals** | : | |
| **Vehicle** | : | |

| | | |
|---|---|---|
| **Doses** | : | |
| **Exposure time** | : | |
| **LC50** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Metal:** No acute inhalation studies have been located for cobalt chloride. |
| **Reliability** | : | |
| **Reference** | : | |

### 5.1.3 ACUTE DERMAL TOXICITY

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Species** | : | |
| **Strain** | : | |
| **Sex** | : | |
| **Number of animals** | : | |
| **Vehicle** | : | |
| **Doses** | : | |
| **LD50** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Metal:** Increased proliferation of lymphatic cells was seen in rats, mice and guinea pigs dermally exposed to cobalt chloride, with LOAEL values ranging from 9.6 to 14.7 mg Co/kg/day. (Appendix C). |
| **Reliability** | : | |
| **Reference** | : | |

### 5.2.1 SKIN IRRITATION

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Species** | : | |
| **Strain** | : | |
| **Sex** | : | |
| **Concentration** | : | |
| **Exposure** | : | |
| **Exposure time** | : | |
| **Number of animals** | : | |
| **Vehicle** | : | |
| **Classification** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |

| | | |
|---|---|---|
| **Remark** | : | **Supporting data for dissociation products:**<br>**Metal:** Dermatitis is a common result of dermal exposure to cobalt in humans and has been verified in a large number of studies. The dermatitis is probably caused by an allergic reaction to cobalt (Appendix C). |
| **Reliability** | : | |
| **Reference** | : | |

### 5.2.2 EYE IRRITATION

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Species** | : | |
| **Strain** | : | |
| **Sex** | : | |
| **Concentration** | : | |
| **Dose** | : | |
| **Exposure time** | : | |
| **Number of animals** | : | |
| **Vehicle** | : | |
| **Classification** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | |
| **Reliability** | : | |
| **Reference** | : | |

### 5.4 REPEATED DOSE TOXICITY

| | | |
|---|---|---|
| **Type** | : | Read across from Co stearate |
| **Guideline/method** | : | |
| **Species** | : | |
| **Strain** | : | |
| **Sex** | : | |
| **Number of animals** | : | |
| **Route of admin.** | : | |
| **Exposure period** | : | |
| **Frequency of treatment** | : | |
| **Post exposure period** | : | |
| **Doses** | : | |
| **Control group** | : | |
| **NOAEL** | : | |
| **LOAEL** | : | |
| **Other** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Acid:** Two repeated dose oral toxicity studies in rats have been conducted using tall oil fatty acids. In a 28-d dietary feeding study, the NOAEL was 15% when expressed in terms of total calories fed (Seppanen, 1969). |

Growth was significantly decreased at a feeding level of 30% of total calories. In a 90-d dietary feeding study, the NOEL was 5% in the diet or approximately 2,500 mg/kg/day (Fancher, 1969). The most sensitive effect was a reduction food consumption (but not body weight) at 10% in the diet. No effects on clinical signs or histopathology were reported at feeding levels up to 25% in the diet.
**Metal:** Repeated oral dosing of rats for 150-210 days with cobalt chloride at 4 and 10 mg Co/kg indicated a LOAEL of 4 mg Co/kg, based upon increased organ weights. Eight weeks' oral exposure of rats to cobalt chloride hexahydrate indicated a LOAEL of 2.5 mg Co/kg (changes in hemoglobin and red blood cell count) and a NOAEL of 0.6 mg Co/kg. Other studies using repeated oral dosing for periods ranging from 12-16 days up to 7 months indicated LOAELs ranging from 0.5 to 30.2 mg Co/kg/day (as cobalt chloride) based upon observations such as reduced weight gain, increases in some organ weights (heart, liver and lungs); increased hematocrit, hemoglobin, and RBCs; renal tubular necrosis; and various changes on cardiac physiology (left ventricular hypertrophy, impaired ventricular function, and degeneration of myofibrils). Cardiac effects were observed in rats at LOAELs ranging from 8.4 to 12.4 mg Co/kg/day, for cobalt sulfate or cobalt chloride, with exposure periods of 3 weeks to 6 months (Appendix C).

**Reliability** :
**Reference** :

### 5.5 GENETIC TOXICITY 'IN VITRO'

**Type** : In Vitro Mammalian Chromosome Aberration Test in Chinese Hamster Ovary Cells

**Guideline/method** : OECD #473
**System of testing** :
**Species** : Chinese Hamster Ovary Cells
**Strain** : CHO-K1 cell line.
**Test concentrations** : 10 to 50 ug/mL
**Cytotoxic concentr.** : 50 ug/mL
**Metabolic activation** : Yes
**Year** : 2007
**GLP** : Yes
**Test substance** : Fatty Acids, Tall-Oil, Cobalt Salt (CAS Number 61789-52-4)

**Method** : OECD #473
**Method detail** :
**Result** : Under the conditions of this study, cobalt tallate was found to induce structural chromosome aberrations in the in vitro mammalian chromosome aberration test in Chinese hamster ovary cells in the non-activated test system only. It was concluded that the test substance was positive in this in vitro test. Based on the findings from the preliminary toxicity assay, the highest concentration chosen for the chromosome aberration assay was 250 µg/mL for all three test conditions. In the chromosome aberration assay, the cells were treated for 4 and 20 hours in the non-activated test condition and for 4 hours in the S9-activated test condition. All cells were harvested 20 hours after treatment initiation. A vehicle control and two positive control groups were included in each test condition. The concentrations initially (trial 1) chosen for the chromosome aberration assay were 10, 25, 50, 100, and 250 µg/mL for all three test conditions. No visible precipitate was observed in the treatment

medium at the beginning or end of the treatment period at any concentration tested. Substantial toxicity was observed at 250 µg/mL in the 4-hour non-activated and activated test conditions (95.4% and 77.1% cell growth reduction, respectively) and at concentrations DuPont-21282 ≥100 µg/mL in the 20-hour non-activated test condition (59.6% cell growth reduction at 100 µg/mL). A decrease in mitotic index of 80.4%, 100%, and 100% was observed at 50, 100, and 250 µg/mL, respectively in the 20-hour non-activated test condition. Because of this excessive toxicity, the assay was repeated (trial 2) for the 20-hour non-activated test condition only. The concentrations chosen for trial 2 of the chromosome aberration assay were 10, 20, 30, 40, and 50 µg/mL for the 20-hour non-activated test condition. In trial 2, no visible precipitate was observed in the treatment medium at the beginning or end of the treatment periods at any concentration tested. Substantial toxicity was not observed at any concentration in trial 2. A reduction in mitotic index of 55.6% was observed at 50 µg/mL. Selection of doses for microscopic analysis was therefore based on these dose concentration levels from trials 1 and 2. Cytogenetic evaluations were conducted at 10, 25, and 50 µg/mL for the 4-hour non-activated and 4-hour S9-activated test conditions and at 10, 30, and 50 µg/mL for the 20-hour non-activated test condition. These concentrations were chosen based on the toxicity data and scorability of the slides (i.e., metaphase quality, chromosome morphology, and a sufficient amount of metaphases present). The percentage of cells with structural aberrations was increased above that of the vehicle control in the 20-hour non-activated test condition at 50 µg/mL ($p < 0.05$, Fisher's exact test).

**Remark** : **Supporting data for dissociation products:**
**Acid:** Tall oil fatty acids tested negative in the Ames *Salmonella*/microsome plate test both with and without metabolic activation (Godek, 1983). Testing was conducted following OECD 471 with five different strains of *S. typhimurium* at doses up to 10,000 µg/plate. In the chromosomal aberration assay with Chinese hamster ovary cells (OECD 473), tall oil fatty acid was clastogenic with S9 mix at 20 ug/mL and without S9 mix at 156 ug/L; both concentrations were overtly toxic to the cells (Murie, 2001). See robust summaries in attached document prepared by the Pine Chemicals Association. (Appendix E).
**Metal:** Cobalt compounds with a valence state of II, the form of cobalt released by dissociation of cobalt chloride, are reported to be generally non-mutagenic in *in vitro* bacterial assays, although weak positive responses have been observed under some conditions (Appendix C).

**Reliability** : [1] without restrictions

**Reference** : Fatty Acids, Tall-Oil, Cobalt Salts: In Vitro Mammalian Chromosome Aberration Test in Chinese Hamster Ovary Cells. (2007). Conducted by DuPont's Haskell Laboratories for the Metal Carboxylates Coalition. Study No. 1641-21282

## 5.6 GENETIC TOXICITY 'IN VIVO'

**Type** :

**Guideline/method** :

| | | |
|---|---|---|
| **Species** | : | |
| **Strain** | : | |
| **Sex** | : | |
| **Route of admin.** | : | |
| **Exposure perriod** | : | |
| **Doses** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Metal:** Cobalt compounds, including soluble salts, are observed to be clastogenic (cause chromosomal aberrations) in a range of mammalian assay systems. Increased micronucleus formation was observed following i.p. injection of 12.4 and 22.3 mg Co/kg (as cobalt chloride), but not after injection of 6.19 mg Co/kg (NOEL). In the mouse micronucleus test, a dose-dependent increase in the frequency of micronucleated polychromatic erythrocytes was observed with i.p. exposure to cobalt chloride hexahydrate (Appendix C). |
| **Reliability** | : | |
| **Reference** | : | |

### 5.8.2 DEVELOPMENTAL TOXICITY

| | | |
|---|---|---|
| **Type** | : | Read across from Co stearate |
| **Guideline/method** | : | |
| **Species** | : | |
| **Strain** | : | |
| **Sex** | : | |
| **Route of admin.** | : | |
| **Exposure period** | : | |
| **Frequency of treatment** | : | |
| **Duration of test** | : | |
| **Doses** | : | |
| **Control group** | : | |
| **NOAEL maternal tox.** | : | |
| **NOAEL teratogen.** | : | |
| **Other** | : | |
| **Other** | : | |
| **Other** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Acid:** The effects of tall oil fatty acids on rat developmental parameters have been studied in a two-generation feeding study (Tegeris, 1975). The study was generally consistent with OECD 416 except the initial treatment period for the parental generation was approximately three weeks prior to mating. Feeding levels were 0, 5, or 10% in the diet. Following weaning, the $F_1$ generation was fed the test article and mated at 100 days. The $F_2$ generation survived to weaning. Treatment did not affect the number of |

liveborn or stillborn $F_1$ litters and pups, or $F_1$ weaning weight. No treatment-related changes in fertility, viability, lactation, or gestation indices were measured. Clinical chemistry and pathological examinations also did not reveal treatment-related effects. It was concluded that tall oil fatty acid had no reproductive or developmental effects on rats at doses as high as 10% (approx. 5,000 mg/kg/day). See robust summary in attached document prepared by the Pine Chemicals Association (Appendix E).
**Metal:** In a developmental toxicity study with cobalt chloride exposure (5.4 or 21.8 mg Co/kg/day) in rats from gestation day 14 to lactation day 21, stunted pup growth was seen at all dose levels. However, maternal toxicity was observed in conjunction with effects on the offspring. This growth effect was considered to be a secondary or indirect effect rather than a direct effect of cobalt on the fetus. No teratogenic effects were observed. Another study in rats provided a NOAEL of 24.8 mg Co/kg/day for cobalt chloride exposure from gestation days 6-15. In a screening study, no effects were observed on fetal growth or survival in mice exposed to 81.7 mg Co/kg/day as cobalt chloride during gestation days 8-12 (Appendix C).

**Reliability** :
**Reference** :

### 5.8.3 TOXICITY TO REPRODUCTION

**Type** : Read across from Co stearate
**Guideline/method** :
**In vitro/in vivo** :
**Species** :
**Strain** :
**Sex** :
**Route of admin.** :
**Exposure period** :
**Frequency of treatment** :
**Duration of test** :
**Doses** :
**Control group** :
**Year** :
**GLP** :
**Test substance** :
**Method** :
**Method detail** :
**Result** :
**Remark** : **Supporting data for dissociation products:**
**Acid:** The effects of tall oil fatty acids on rat reproductive parameters have been studied in a two-generation feeding study (Tegeris, 1975). The study was generally consistent with OECD 416 except the initial treatment period for the parental generation was approximately three weeks prior to mating. Feeding levels were 0, 5, or 10% in the diet. Following weaning, the $F_1$ generation was fed the test article and mated at 100 days. The $F_2$ generation survived to weaning. Treatment did not affect the number of liveborn or stillborn $F_1$ litters and pups, or $F_1$ weaning weight. No treatment-related changes in fertility, viability, lactation, or gestation indices were measured. Clinical chemistry and pathological examinations also did not reveal treatment-related effects. It was concluded that tall oil fatty acid had no reproductive or developmental effects on rats at doses as high as 10% (approx. 5,000 mg/kg/day). See robust summary in attached document prepared by the Pine Chemicals Association (Appendix E).
**Metal:** Male mice exposed to cobalt chloride hexahydrate in drinking water for 12-13 weeks demonstrated effects on testicular weight and sperm

concentration at all dose levels (23 – 58.9 mg Co/kg bw). Rats exposed to 20 mg Co/kg bw (as cobalt chloride hexahydrate) through the diet showed degenerative and necrotic lesions in seminiferous tubles and testicular atrophy (Appendix C).

**Reliability** :
**Reference** :

## 6.0 OTHER INFORMATION

**Supporting data for dissociation products:**
**Acid:** A safety assessment of tall oil acid (a purified form of tall oil fatty acids) has been performed for use in cosmetic products by an Expert Panel (Expert Panel, 1989). Based on its review of available data for tall oil acid and its primary constituent (oleic acid), the Expert Panel concluded that tall oil acid is safe for use in cosmetics. The Expert Report includes a clinical assessment of safety for dermal exposure based on testing in human subjects. Several studies were conducted with liquid soaps containing 12% tall oil acid. These studies included a 4-week hand washing study with a diluted soap (final concentration of 3% tall oil acid) and two repeated dose patch studies with undiluted soap. None of the subjects in these studies had positive reactions and the soap was found to be non-irritating and non-sensitizing.

Expert Panel. 1989. Final report on the safety assessment of tall oil acid. J. Amer. Coll. Toxicol. 8:769-776.

## 6.1 CARCINOGENICITY

**Supporting data for dissociation products:**
**Metal:** The US National Toxicology Program does not recognize cobalt as a human carcinogen, but IARC has classified cobalt and cobalt compounds as possibly carcinogenic to humans (Class 2B) based on sufficient evidence that cobalt metal powder and cobaltous oxide are carcinogenic in animals (Barceloux 1999, ATSDR Sept 2001 Draft). “No studies were located regarding carcinogenic effects in animals after oral exposure to stable [non-radioactive] cobalt.” (ATSDR Sept 2001 Draft).

## 1. General Information

**ID** 7646-79-9

**Date** January 31, 2005

# Appendix C: Cobalt Chloride

Prepared by the Metal Carboxylates Coalition



### 1.0 SUBSTANCE INFORMATION

| | | |
|---|---|---|
| **Generic Name** | : | Cobalt chloride |
| **Chemical Name** | : | Cobaltous chloride |
| **CAS Registry No.** | : | 7646-79-9 |
| **Component CAS Nos.** | : | |
| **EINECS No.** | : | |
| **Structural Formula** | : | $CoCl_2$ |
| **Molecular Weight** | : | 129.84 |
| **Synonyms and Tradenames** | : | Cobalt(II) chloride; Cobalt dichloride |
| **References** | : | ATSDR, 2001. Draft Toxicological Profile for Cobalt, U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry (ATSDR), September 2001. (This reference is subsequently listed in this document as ATSDR Sept 2001 Draft). |

### 2.1 MELTING POINT

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Value** | : | 735 °C |
| **Decomposition** | : | at °C |
| **Sublimation** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | Decomposes at 400 °C on long heating in air |
| **Reliability** | : | 2 (reliable with restrictions): Source is well established data compendium. |
| **Reference** | : | O'Neil, M.J., Smith, A., Heckelman, P.E., and J.R. Obenchain (eds.). 2002. The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals. 13th Ed. Merck & Co., Inc., Whitehouse Station, NJ |

### 2.2 BOILING POINT

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Value** | : | 1,049 °C |
| **Decomposition** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | |
| **Reliability** | : | 2 (reliable with restrictions): Source is well established data compendium. |
| **Reference** | : | O'Neil, M.J., Smith, A., Heckelman, P.E., and J.R. Obenchain (eds.). 2002. The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals. 13th Ed. Merck & Co., Inc., Whitehouse Station, NJ |

### 2.3 DENSITY

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Value** | : | 3.367 at 25 °C |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | |
| **Reliability** | : | 2 (reliable with restrictions): Source is well established data compendium. |
| **Reference** | : | O'Neil, M.J., Smith, A., Heckelman, P.E., and J.R. Obenchain (eds.). 2002. The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals. 13th Ed. Merck & Co., Inc., Whitehouse Station, NJ |

### 2.4 VAPOR PRESSURE

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Value** | : | hPa at °C |
| **Decomposition** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | |
| **Reliability** | : | |
| **Reference** | : | |

### 2.5 PARTITION COEFFICIENT

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Partition coefficient** | : | |
| **Log Pow** | : | at °C |
| **pH value** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | Not applicable – metal dissociates (ionizes) in water |
| **Reliability** | : | |
| **Reference** | : | |

### 2.6.1 SOLUBILITY IN WATER

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Value** | : | 450 g/L at 7 °C |
| **pH value** | : | |
| **concentration** | : | at °C |
| **Temperature effects** | : | |
| **Examine different pol.** | : | |
| **PKa** | : | at °C |
| **Description** | : | |
| **Stable** | : | |
| **Deg. product** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Deg. products CAS#** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | 544 g/L in ethanol; 86 g/L in acetone |
| **Reliability** | : | 2 (reliable with restrictions): Source is well established data compendium |
| **Reference** | : | Weast. R.C. (ed.). 1988-1989. Handbook of Chemistry and Physics. 69th Ed. CRC Press Inc., Boca Raton, FL., p. B-86. |

### 2.7 FLASH POINT

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Value** | : | °C |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | |
| **Reliability** | : | |
| **Reference** | : | |

### 3.1.1 PHOTODEGRADATION

| | | |
|---|---|---|
| **Type** | | |
| **Guideline/method** | : | |
| **Light source** | : | |
| **Light spectrum** | : | |
| **Relative intensity** | : | based on |
| **Spectrum of substance** | : | lambda (max, >295nm) : |
| | | epsilon (max) : |
| | | epsilon (295) : |
| **Conc. of substance** | : | at °C |
| **DIRECT PHOTOLYSIS** | | |
| **Halflife (t1/2)** | : | |
| **Degradation** | : | % after |
| **Quantum yield** | : | |
| **INDIRECT PHOTOLYSIS** | | |
| **Sensitizer** | : | |
| **Conc. of sensitizer** | : | |
| **Rate constant** | : | |
| **Degradation** | : | |
| **Deg. product** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Deg. products CAS#** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | Not applicable – metal does not degrade |
| **Reliability** | : | |
| **Reference** | : | |

### 3.2.1 MONITORING DATA

| | | |
|---|---|---|
| **Type of measurement** | : | |
| **Media** | : | |
| **Concentration** | : | |
| **Substance measured** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | |
| **Reliability** | : | |
| **Reference** | : | |

### 3.3.1 TRANSPORT (FUGACITY)

| | | |
|---|---|---|
| **Type** | : | |
| **Media** | : | |
| **Air** | : | % (Fugacity Model Level I) |
| **Water** | : | % (Fugacity Model Level I) |
| **Soil** | : | % (Fugacity Model Level I) |
| **Biota** | : | % (Fugacity Model Level II/III) |
| **Soil** | : | % (Fugacity Model Level II/III) |
| **Year** | : | |
| **Test substance** | : | |
| **Method** | : | |

**Method detail** :
**Result** :
**Remark** :
**Reliability** :
**Reference** :

### 3.5 BIODEGRADATION

**Type** :
**Guideline/method** :
**Inoculum** :
**Concentration** : related to
related to
**Contact time** :
**Degradation** : (±) % after day(s)
**Result** :
**Kinetic of test subst.** : % (specify time and % degradation)
%
%
%
%
**Control substance** :
**Kinetic** : %
%
**Deg. product** :
**Year** :
**GLP** :
**Test substance** :
**Deg. products CAS#** :
**Method** :
**Method detail** :
**Result** :
**Remark** : Not applicable – the metal will not degrade
**Reliability** :
**Reference** :

### 3.7 BIOCONCENTRATION

**Type** :
**Guideline/method** :
**Species** :
**Exposure period** : at °C
**Concentration** :
**BCF** :
**Elimination** :
**Year** :
**GLP** :
**Test substance** :
**Method** :
**Method detail** :
**Result** :
**Remark** :
**Reliability** :
**Reference** :

## 4.1 ACUTE TOXICITY TO FISH

| | | |
|---|---|---|
| **Type** | : | Acute |
| **Guideline/method** | : | Flow-through, freshwater |
| **Species** | : | Rainbow trout (*Onchorhynchus mykiss*) |
| **Exposure period** | : | 96 hr |
| **NOEC** | : | |
| **LC0** | : | |
| **LC50** | : | 1.41 mg Co/L (95% C.I. = 0.57 – 3.47 mg Co/L) |
| **LC100** | : | |
| **Other** | : | LC20 = 0.53 mg Co/L (95% C.I. = 0.24 – 1.20 mg Co/L) |
| **Other** | : | Incipient lethal level for 50% mortality (time independent) = 0.35 mg Co/L |
| **Other** | : | 144-hr LC50 = 0.52 mg Co/L (95% C.I. = 0.29 – 0.95 mg Co/L) |
| **Limit test** | : | |
| **Analytical monitoring** | : | Yes (results based on measured concentrations) |
| **Year** | : | 1998 |
| **GLP** | : | No |
| **Test substance** | : | Cobalt chloride dihydrate ($CoCl_2 \cdot 2H_20$) |
| **Method** | : | |
| **Method detail** | : | Tests were conducted with trout fry in water with an alkalinity and hardness of approximately 25 mg $CaCO_3$/L. Exposure concentrations ranged from 0.125 to 2.0 mg Co/L. Exposures were continued for up to 14 days, with mortality assessed every 2 hr for the first 48 hr, and every 6 h thereafter. |
| **Result** | : | The onset of mortality was slow (48 hr or greater), generally not reaching a plateau for 200 hr or more. |
| **Remark** | : | Study data indicate that the rainbow trout is highly sensitive to the toxic effects of cobalt. For comparison, reported 96-h LC50 values for other fish species include 22.0 mg Co/L for the fathead mninnow (*Pimephales promelas*), 333 mg Co/L for the carp (*Cyprinus carpio*), and 275 mg Co/L for the mummichog (*Fundulus heteroclitus*) (U.S. EPA, ECOTOX data base, 2003). Available data suggest that toxicity to fish is reduced with increasing hardness up to a hardness of approximately 400 mg $CaCO_3$/L (Diamond, J. et al., 1992. Aquat. Toxicol., 22:163-180). |
| **Reliability** | : | 2 (Reliable with restrictions): comparable to guideline study |
| **Reference** | : | Marr, J.C.A., J.A. Hansen, J.S. Meyer, D. Cacela, T. Podrabsky, J. Lipton, and H.L. Bergman. 1998. Toxicity of cobalt and copper to rainbow trout: application of a mechanistic model for predicting survival. Aquat. Toxicol., 43(4):225-238. |

## 4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

| | | |
|---|---|---|
| **Type** | : | Acute |
| **Guideline/method** | : | Static, freshwater |
| **Species** | : | *Daphnia magna* (water flea) |
| **Exposure period** | : | 48 hr |
| **NOEC** | : | |
| **EC0** | : | |
| **EC50** | : | 1.52 mg Co/L (95% C.I. = 1.01 - 2.28 mg Co/L) |
| **EC100** | : | |
| **Other** | : | 24 hr LC50 = 2.11 mg Co/L (95% C.I. = 1.49 - 3.05 mg Co/L) |
| **Other** | : | |
| **Other** | : | |
| **Limit test** | : | |
| **Analytical monitoring** | : | No |
| **Year** | : | 1987 |
| **GLP** | : | No |
| **Test substance** | : | Cobalt chloride hexahydrate ($CoCl_2 \cdot 6H_20$) |

| | | |
|---|---|---|
| **Method** | : | American Public Health Association (APHA), 1976, Standard Methods for the Examination of Water and Wastewater. |
| **Method detail** | : | Tests were conducted in well water with a total hardness of 240 mg $CaCO_3$/L and a total alkalinity of 400 mg $CaCO_3$/L. Solutions were not renewed during the test. Daphnids were not fed during the test. |
| **Result** | : | |
| **Remark** | : | In an older study, the 48-hr LC50 for *Daphnia magna* has been reported as 5.5 mg Co/L (Cabejszek and Stasiak, 1960 as cited in the U.S. EPA ECOTOX database, 2003). The 48-hr LC50 for another daphnid, *Daphnia hyaline*, has been reported as 1.52 mg Co/L (Baudouin and Scoppa, 1974 as cited in the U.S. EPA ECOTOX database, 2003). Others have found 48-hr LC50 values for *Ceriodaphnia dubia* of 2.35, 4.60, and 4.20 mg Co/L for tests conducted with water hardness of 50, 200, and 400 mg $CaCO_3$/L, respectively (Diamond, J. et al., 1992. Aquat. Toxicol., 22:163-180). |
| **Reliability** | : | 2 (Reliable with restrictions): comparable to guideline study |
| **Reference** | : | Khangarot, B.S., P.K. Ray, and H. Chandra. 1987. *Daphnia magna* as a model to assess heavy metal toxicity: comparative assessment with mouse system. Acta. Hydrochim. Hydrobiol., 15(4): 427-432. |

### 4.3 TOXICITY TO AQUATIC PLANTS (E.G., ALGAE)

| | | |
|---|---|---|
| **Type** | : | Algal growth assay |
| **Guideline/method** | : | Static, freshwater |
| **Species** | : | *Chlorella vulgaris* (green algae) |
| **Endpoint** | : | Population growth |
| **Exposure period** | : | 96 hr |
| **NOEC** | : | |
| **LOEC** | : | |
| **EC0** | : | |
| **EC10** | : | |
| **EC50** | : | 0.52 mg Co/L (95% C.I. = 0.48 – 0.56 mg Co/L) |
| **Other** | : | |
| **Other** | : | |
| **Other** | : | |
| **Limit test** | : | |
| **Analytical monitoring** | : | No |
| **Year** | : | 1993 |
| **GLP** | : | |
| **Test substance** | : | Cobalt chloride |
| **Method** | : | |
| **Method detail** | : | Tests conducted in modified Bristol's medium (pH 6.5) with a 16:8 day/night photoperiod (280 foot candles). Cultures were incubated at 19°C ± 1°C. Results were based on experiments run in triplicate. |
| **Result** | : | Growth was 63.8% and 28.4% of controls at concentrations of 0.32 and 1.00 mg Co/L, respectively. |
| **Remark** | : | Other aquatic plants are much less sensitive to cobalt. The reported 96-h EC50 for *Spirulina platensis* (blue-green algae) is 23.8 mg Co/L (Sharma et al., 1987 as cited in the U.S. EPA ECOTOX database, 2003). The 7-d IC50 for *Lemna minor* (duckweed) is 16.9 mg Co/L (Dirilgen and Inel, 1994 as cited in the U.S. EPA ECOTOX database, 2003). |
| **Reliability** | : | 2 (reliable with restrictions); comparable to guideline study |
| **Reference** | : | Rachlin, J.W. and A. Grosso. 1993. The growth response of the green alga *Chlorella vulgaris* to combined divalent cation exposure. Arch. Environ. Contam. Toxicol., 24: 16-20. |

## 5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

| | | |
|---|---|---|
| **In vitro/in vivo** | : | |
| **Type** | : | |
| **Guideline/method** | : | |
| **Species** | : | |
| **Number of animals** | : | |
| **Males** | : | |
| **Females** | : | |
| **Doses** | : | |
| **Males** | : | |
| **Females** | : | |
| **Vehicle** | : | |
| **Route of administration** | : | |
| **Exposure time** | : | |
| **Product type guidance** | : | |
| **Decision on results on acute tox. tests** | : | |
| **Adverse effects on prolonged exposure** | : | |
| **Half-lives** | : | 1st.:<br>2nd.:<br>3rd.: |
| **Toxic behavior** | : | |
| **Deg. product** | : | |
| **Deg. products CAS#** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | Absorption of cobalt in the digestive tract is influenced by the chemical form of the metal, with increasing solubility resulting in increasing absorption (ATSDR Sept 2001 Draft). Approximately 13-34% of cobalt chloride, a soluble form, is absorbed in the gut of rats, but absorption in the gut may be increased in iron deficient individuals. Following oral exposure, cobalt is eliminated primarily in feces and secondarily in urine. For the more soluble forms of cobalt, e.g., cobalt chloride, 70 – 80% of the administered dose is eliminated in the feces. For absorbed cobalt, elimination is rapid primarily in the urine (Barceloux, D.G. 1999. Cobalt. Clin. Tox. 37:201-206). Elimination is biphasic or triphasic. The terminal phase involves a very small residual level of cobalt and has a half-life in years (ATSDR Sept 2001 Draft). |
| **Reliability** | : | |
| **Reference** | : | |

### 5.1.1 ACUTE ORAL TOXICITY

| | | |
|---|---|---|
| **Type** | : | Oral |
| **Guideline/Method** | : | Not specified |
| **Species** | : | Rat |
| **Strain** | : | Wistar |
| **Sex** | : | Male and female |
| **Number of animals** | : | 5 per sex per dose level |
| **Vehicle** | : | Distilled water |
| **Doses** | : | 50, 600, 720, 864, and 1137 mg/kg |

| | | |
|---|---|---|
| **LD50** | : | 766 mg/kg as compound (hexahydrate); 95% C.I. = 677 – 867 mg/kg)<br>190 mg/kg as cobalt |
| **Year** | : | 1982 |
| **GLP** | : | No |
| **Test substance** | : | Cobalt(II) chloride hexahydrate ($CoCl_2 \cdot 6H_20$) |
| **Method** | : | Single dose administered by gastric incubation |
| **Method detail** | : | Mortality assessed after a 10-d observation period. |
| **Result** | : | |
| **Remark** | : | Reported LD50s of cobalt chloride to rats range from 42.4 to 190 mg Co/kg bw (ATSDR Sept 2001 Draft). Toxicity of cobalt sulfate is reported to be similar to that of the chloride with oral LD50s for rats ranging from 123 to 161 Co/kg bw)(ATSDR Sept 2001 Draft). For the mouse, LD50 values are 89.3 and 123 mg Co/kg for cobalt chloride and cobalt sulfate (ATSDR Sept 2001 Draft). |
| **Reliability** | : | 2 (Reliable with restrictions): comparable to guideline study with adequate documentation. |
| **Reference** | : | Speijers, G.J.A., E.I. Krajnc, J.M. Berkvens, and M.J. van Logten. 1982. Acute oral toxicity of inorganic cobalt compounds in rats. Food Chem. Toxicol., 20:311-314. |

### 5.1.2 ACUTE INHALATION TOXICITY

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Species** | : | |
| **Strain** | : | |
| **Sex** | : | |
| **Number of animals** | : | |
| **Vehicle** | : | |
| **Doses** | : | |
| **Exposure time** | : | |
| **LC50** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | No acute toxicity studies have been located for this compound. |
| **Reliability** | : | |
| **Reference** | : | |

### 5.1.3 ACUTE DERMAL TOXICITY

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Species** | : | |
| **Strain** | : | |
| **Sex** | : | |
| **Number of animals** | : | |
| **Vehicle** | : | |
| **Doses** | : | |
| **LD50** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |

| | | |
|---|---|---|
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | Increased proliferation of lymphatic cells was seen in rats, mice and guinea pigs dermally exposed to cobalt chloride in DMSO once per day for 3 consecutive days, with LOAEL values ranging from 9.6 to 14.7 mg Co/kg/day (Ikarashi, Y., et al., 1992. Toxicology, 76:283-292). Stimulation indices of 3 or greater (indicative of a significant response by the authors), were reported for mice exposed to 1, 2.5 or 5% $CoCl_2$ (equivalent to 10.8, 27, or 54.1 mg Co/kg/day), rats exposed to 2.5 or 5% $CoCl_2$ (equivalent to 9.6 or 19.2 mg Co/kg/day), and guinea pigs exposed to 5% $CoCl_2$ (equivalent to 14.7 mg Co/kg/day). |
| **Reliability** | : | |
| **Reference** | : | |

### 5.2.1 SKIN IRRITATION

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Species** | : | |
| **Strain** | : | |
| **Sex** | : | |
| **Concentration** | : | |
| **Exposure** | : | |
| **Exposure time** | : | |
| **Number of animals** | : | |
| **Vehicle** | : | |
| **Classification** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | Dermatitis is a common result of dermal exposure to cobalt in humans and has been verified in a large number of studies (ATSDR Sept 2001 Draft). The dermatitis is probably caused by an allergic reaction to cobalt. |
| **Reliability** | : | |
| **Reference** | : | |

### 5.2.2 EYE IRRITATION

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Species** | : | |
| **Strain** | : | |
| **Sex** | : | |
| **Concentration** | : | |
| **Dose** | : | |
| **Exposure time** | : | |
| **Number of animals** | : | |
| **Vehicle** | : | |
| **Classification** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |

| | | |
|---|---|---|
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | |
| **Reliability** | : | |
| **Reference** | : | |

### 5.4 REPEATED DOSE TOXICITY

| | | |
|---|---|---|
| **Type** | : | Repeated dose |
| **Guideline/method** | : | Oral |
| **Species** | : | Rat |
| **Strain** | : | Not specified |
| **Sex** | : | Male |
| **Number of animals** | : | 30 |
| **Route of admin.** | : | Oral via stomach tube |
| **Exposure period** | : | 150 to 210 days |
| **Frequency of treatment** | : | Five days per week |
| **Post exposure period** | : | 0 to 30 days |
| **Doses** | : | 4 or 10 mg Co/kg |
| **Control group** | : | Yes |
| **NOAEL** | : | |
| **LOAEL** | : | 4 mg Co/kg (organ weights increased) |
| **Other** | : | |
| **Year** | : | 1959 |
| **GLP** | : | No |
| **Test substance** | : | Cobalt chloride |
| **Method** | : | |
| **Method detail** | : | The erythrocyte count, hemoglobin and hematocrit determinations were performed at frequent intervals for animals receiving 10 mg Co/kg. At study termination, all rats were sacrificed, organs examined and weighed, and sections made histological examination. |
| **Result** | : | The average weights of kidneys, livers, and spleens of the cobalt-treated groups were slightly heavier than the controls. Cobalt exposure at 10 mg/kg produced significant polycythemia. Histological examination of the kidneys revealed necrosis of the linings of the tubules in rats treated with 10 mg Co/kg, but not in those of the 4 mg Co/kg group. The effects was reversible, however, as examination of kidneys of rats autopsied 30 days after cobalt administration was discontinued showed no necrosis and were normal compared to the kidneys from control rats. |
| **Remark** | : | Results are highly consistent with those reported by others. Repeated oral dosing of rats with cobalt chloride at levels ranging from 0.5 to 30.2 mg Co/kg/day (as cobalt chloride) for periods ranging from 12-16 days up to 7 months resulted in the following observations associated with LOAELs: reduced weight gain, increases in some organ weights (heart, liver and lungs); increased hematocrit, hemoglobin, and red blood cells; renal tubular necrosis; and various changes on cardiac physiology (left ventricular hypertrophy, impaired ventricular function, and degeneration of myofibrils) (ATSDR Sept 2001 Draft). Cardiac effects were observed in rats at LOAEL's ranging from 8.4 to 12.4 mg Co/kg/day, for cobalt sulfate or cobalt chloride, with exposure periods of 3 weeks to 6 months (ATSDR Sept 2001 Draft). |
| **Reliability** | : | 2 (Reliable with restrictions): comparable to guideline study with adequate documentation. |
| **Reference** | : | Murdock, H.R. 1959. Studies on the pharmacology of cobalt chloride. J. Amer. Pharm. Assoc., 48:140-142. |

| | | |
|---|---|---|
| **Type** | : | Repeated dose |

| | | |
|---|---|---|
| **Guideline/method** | : | Not specified |
| **Species** | : | Rat |
| **Strain** | : | Sprague-Dawley |
| **Sex** | : | Male |
| **Number of animals** | : | 4 |
| **Route of admin.** | : | Oral |
| **Exposure period** | : | 8 weeks |
| **Frequency of treatment** | : | Daily |
| **Post exposure period** | : | None |
| **Doses** | : | 2.5, 10, or 40 mg/kg (equivalent to 0.6, 2.5, or 10 mg Co/kg) |
| **Control group** | : | Yes |
| **NOAEL** | : | 0.6 mg Co/kg |
| **LOAEL** | : | 2.5 mg Co/kg (hemoglobin, red blood cell count) |
| **Other** | : | |
| **Year** | : | 1947 |
| **GLP** | : | No |
| **Test substance** | : | Cobalt chloride hexahydrate ($CoCl_2 \cdot 6H_20$) |
| **Method** | : | |
| **Method detail** | : | Cobalt was administered orally in a gelatin capsule (mixed in equal part of wheat flour and powdered sugar). Blood counts and hemoglobin determinations were made at the start of the test and at two week intervals. |
| **Result** | : | Hemoglobin content and numbers of erythrocytes were increased in rats receiving either 2.5 or 10 mg Co/kg/day, but not in those receiving 0.6 mg Co/kg/day. |
| **Remarks** | : | Other researchers have reported similar results in long-term studies with rats although many study details are lacking in the published report (Krasovskii, G.N. and S.A. Fridlyand. 1971. Hyg. Sanit., 26:277-279). They found that oral doses of 0.5 and 2.5 mg Co/kg six days per week for seven months stimulated hemopoiesis and decreased immunological reactivity (reduced the phagocytic index). Daily doses of 0.5 mg Co/kg and greater also produced mild to moderate increases in conditioned flexes. However, daily doses of 0.05 mg Co/kg had no effects on the indices investigated. Others have also reported the neurotoxic and behavior effects of cobalt on rats after chronic dietary exposures (Nation, J.R. et al., 1983. Neurobehav. Toxicol. Teratol., 5:9-15). |
| **Reliability** | : | 2 (reliable with restrictions): Documentation was incomplete; however, the results are highly consistent with others in the scientific literature. |
| **Reference** | : | Stanley, A.J., H.C. Hopps, and A.M. Shideler. 1947. Cobalt polycythemia. II. Relative effects of oral and subcutaneous administration of cobaltous chloride. Proc. Soc. Exp. Biol. Med., 66:19-20. |

### 5.5 GENETIC TOXICITY - MUTAGENICITY

| | | |
|---|---|---|
| **Type** | : | Mutagenicity |
| **Guideline/method** | : | Ames Assay |
| **System of testing** | : | Bacteria *in vitro* |
| **Species** | : | *Salmonella typhimurium* LT2 |
| **Strains** | : | TA100 |
| **Test concentrations** | : | $10^{-4}$ to $10^{-1}$ M |
| **Cytotoxic concentr.** | : | $10^{-2}$ M |
| **Metabolic activation** | : | No |
| **Year** | : | 1981 |
| **GLP** | : | No |
| **Test substance** | : | Cobalt chloride hexahydrate ($CoCl_2 \cdot 6H_20$) |
| **Method** | : | Ames, B.N., J. McCann, and E. Yamasaki. 1975. Mutat. Res., 31:347-364. |
| **Method detail** | : | |

| | | |
|---|---|---|
| **Result** | : | Negative both above and below the cytotoxic concentration |
| **Remark** | : | Cobalt compounds with a valence state of II, the form of cobalt released by dissociation of cobalt chloride, are generally nonmutagenic in *in vitro* bacterial assays (ATSDR Sept 2001 Draft). For example, cobalt chloride was not mutagenic in plate incorporation and fluctuation assays with *Salmonella* TA strains or a *Escherichia coli* WP2 strain (Arlauskas, A., et al., 1985. Environ. Res., 36:379-388). However, a weak positive mutagenic response has been found in the rec assay with *Bacillus subtilis* at a concentration of 0.05 M (Kanematsu, N. et al., 1980. Mutat. Res., 77:109-116). A very weak positive response has also been found in Chinese hamster V79 cells, but only at a highly cytotoxic concentration (Miyaki, M. et al. 1979. Mutat. Res., 68: 259-263). |
| **Reliability** | : | 2 (Reliable with restrictions): comparable to guideline study with adequate documentation. |
| **Reference** | : | Tso, W-W. and W-P Fung. 1981. Mutagenicity of metallic cations. Toxicolog. Lett., 8:195-200. |

| | | |
|---|---|---|
| **Type** | : | Mutagenicity |
| **Guideline/method** | : | Ames Assay |
| **System of testing** | : | Bacteria *in vitro* |
| **Species** | : | *Salmonella typhimurium* LT2 |
| **Strains** | : | TA98, TA100, TA1537, and TA2637 |
| **Test concentrations** | : | 0.1 to 1,000 µM/plate |
| **Cytotoxic conc.** | : | Not specified |
| **Metabolic activation** | : | No |
| **Year** | : | 1986 |
| **GLP** | : | No |
| **Test substance** | : | Cobalt chloride |
| **Method** | : | Ames, B.N., J. McCann, and E. Yamasaki. 1975. Mutat. Res., 31:347-364. |
| **Method detail** | : | A modified Tris-HCl minimal medium with low phosphate content was used to prevent formation of insoluble metal phosphates in the test system. |
| **Result** | : | Negative |
| **Remark** | : | Although cobalt chloride alone did not produce mutants in this test system, it was mutagenic when it was added as a mixture with one of several heteroaromatic compounds (e.g., 4-aminoquinoline, 9-aminoacridine). The enhanced mutagenicity was attributed by the authors to the formation of weak to moderate complexes between these chemicals and the Co(II) cation, which may have enhanced transmembrane permeation or intercellular binding. |
| **Reliability** | : | 2 (Reliable with restrictions): comparable to guideline study with adequate documentation. |
| **Reference** | : | Ogawa, H.I., K. Sakata, T. Inouye, S. Jyosui, Y. Niyitani, K. Kamimoto, M. Morishita, S. Tsuruta, and Y. Kato. 1986. Combined mutagenicity of cobalt(II) salt and heteroaromatic compounds in *Salmonella typhimurium*. Mutat. Res., 172: 97-104. |

## 5.6 GENETIC TOXICITY - CLASTOGENICITY

| | | |
|---|---|---|
| **Type** | : | Chromosomal aberrations in bone marrow cells |
| **Guideline/method** | : | *In vivo* |
| **Species** | : | Mouse (*Mus musculus*) |
| **Strain** | : | Swiss albino |
| **Sex** | : | Male |
| **Route of admin.** | : | Oral (single dose) |
| **Exposure period** | : | 6, 12, 18, or 24 hr. |
| **Dose** | : | 20, 40 , or 80 mg/kg b.w. |
| **Year** | : | 1991 |
| **GLP** | : | No |
| **Test substance** | : | Cobalt chloride hexahydrate ($CoCl_2 \cdot 6H_20$) |
| **Method** | : | Preston, R.J. et al., 1987. Mutat. Res., 189:157. |
| **Method detail** | : | Test compound was administered orally to five animals per dose group. Mice were 6-8 weeks old at that time. Colchicine (0.04%) was injected i.p. at 90 min prior to sacrifice. Bone marrow cells were removed form femurs by flushing with 0.8% sodium citrate. From each animal, 50 well-scattered metaphase plate were scored for chromosomal aberrations. Abnormalities were scored separately as total aberrations (with and without gaps) and as breaks per cell. |
| **Result** | : | Administration of cobalt chloride produced a concentration-dependent increase in total chromosomal aberrations. |
| **Remark** | : | Cobalt compounds, including soluble salts, are observed to be clastogenic (cause chromosomal aberrations) in a range of mammalian assay systems. For example, increased micronucleus formation was observed following i.p. injection of 12.4 and 22.3 mg Co/kg (as cobalt chloride), but not after injection of 6.19 mg Co/kg (NOEL) (ATSDR Sept 2001 Draft). There is evidence that soluble cobalt(II) cations exert a genotoxic activity in vitro and in vivo in experimental systems, but evidence in humans is lacking (Lison, D. et al., 2001. Occup. Environ. Med., 58: 619-625). |
| **Reliability** | : | 2 (Reliable with restrictions): comparable to guideline study with adequate documentation. |
| **Reference** | : | Palit, S., A. Sharma, and G. Talukder. 1991. Chromosomal aberrations induced by cobaltous chloride in mice in vivo. Biol. Trace Elem. Res., 29:139-145. |

| | | |
|---|---|---|
| **Type** | : | Micronucleus Test |
| **Guideline/method** | : | In vivo |
| **Species** | : | Mouse |
| **Strain** | : | BALB/c AnNCRj |
| **Sex** | : | Male |
| **Route of admin.** | : | Intraperitoneally |
| **Exposure period** | : | 30 hr |
| **Doses** | : | 25, 50, or 90 mg Co/kg b.w. |
| **Year** | : | 1993 |
| **GLP** | : | No |
| **Test substance** | : | Cobalt chloride hexahydrate ($CoCl_2 \cdot 6H_20$) |
| **Method** | : | Von Ledbur, M. and W. Schmid. 1973. Mutat. Res., 19:109-117. |
| **Method detail** | : | Mice were injected once ip and sacrificed after 30 hr. Bone marrow smears were prepared and stained. The incidence of micronucleated polychromatic erythrocytes (MPCE) was determined in 1,000 cells. In addition, the ratio of polychromatic erythrocytes (P) to normochromatic erythrocytes (N) was determined in 2,000 erythrocytes. |
| **Result** | : | Treatment with cobalt induced a dose-dependent increase in the frequency of MPCE. The P/N ratio was significantly reduced ($P<0.05$) in mice dosed at 90 mg/kg b.w. |

| | | |
|---|---|---|
| **Remark** | : | This study also included an *in vitro* micronucleus test with mouse bone marrow cells, both with and without metabolic activation with an S9 fraction. In contrast to the *in vivo* test, the *in vitro* test did not produce any significant changes in frequency of MPCE or the P/N ratio at dose levels of cobalt chloride hexahydrate up to 50 mg/L in the cell suspension. |
| **Reliability** | : | 2 (Reliable with restrictions): comparable to guideline study with adequate documentation. |
| **Reference** | : | Suzuki, Y., H. Shimizu, Y. Nagae, M. Fukumoto, H. Okonogi, and M. Kadokura. 1993. Micronucleus test and erythropoiesis: effect of cobalt on the induction of micronuclei by mutagens. Environ. Mol. Mutagen., 22:101-106. |
| **Type** | : | DNA damage in isolated human lymphocytes |
| **Guideline/method** | : | Alkaline Comet Assay (*in vitro*) |
| **Species** | : | Human |
| **Strain** | : | |
| **Sex** | : | Female |
| **Route of admin.** | : | In vitro |
| **Exposure period** | : | 15 min |
| **Doses** | : | 0.3, 0.6, 1.2, 1.5, 2.0, 2.5, 3.0, and 6.0 mg Co/L |
| **Year** | : | 1998 |
| **GLP** | : | No |
| **Test substance** | : | Cobalt chloride hexahydrate ($CoCl_2 \cdot 6H_20$) |
| **Method** | : | The alkaline comet assay performed using a modification of the method of Singh et al. 1988. Exp. Cell. Res., 175:184-191. |
| **Method detail** | : | Tests were conducted on lymphocytes taken from two healthy female donors. Cells were for 15 min exposed after 24 of stimulation by phytohaemagglutinin. After treatment, the cells were centrifuged for 10 min at 400 g. The supernatant was removed and the cell pellet was resuspended and processed for the alkaline comet assay (single cell electrophoresis assay). Fifty or 100 randomly selected slides were analyzed, with tail length, tail DNA, and tail movement recorded. |
| **Result** | : | There was considerable interexperimental and interdonor variability in data; however, at the highest dose level (6.0 mg Co/L) there was a statistically significant increase in tail movement in all experiments, indicating DNA damage (single strand breaks and alkali labile sites). Tail movement was also increased at lower doses, but did not show a clear dose-dependent trend. |
| **Remark** | : | Using human lymphocytes and macrophages ($P388D_1$ cells), an increase in sister chromatid exchanges (SCE) after exposure to cobalt chloride at $10^{-4}$ to $10^{-5}$ M has been also demonstrated (Andersen, O. 1983. Environ. Health Perspect., 47: 239-253). Others have also found that cobalt chloride increases DNA strand breaks in human diploid fibroblasts and Chinese hamster ovary cells after *in vitro* exposures, although only when determined by alkaline sediment sucrose velocity sedimentation and not when measured by nucleoid sedimentation or nick translation assays (Hamilton-Koch, W. et al., 1986. Chem.-Biol. Interactions, 59:17-28). |
| **Reliability** | : | 2 (Reliable with restrictions): comparable to guideline study with adequate documentation. |
| **Reference** | : | De Beck, M., D. Lison, and M. Kirsch-Volders. 1998. Evaluation of the in vitro direct and indirect genotoxic effects of cobalt compounds using the alkaline comet assay. Influence of interdonor and interexperimental variability. Carcinogenesis, 19:2021-2029. |

### 5.8.2 DEVELOPMENTAL TOXICITY

| | | |
|---|---|---|
| **Type** | : | Developmental toxicity |
| **Guideline/method** | : | Not specified |
| **Species** | : | Rat |
| **Strain** | : | Wistar |
| **Sex** | : | Female |
| **Route of admin.** | : | Gastric intubation |
| **Exposure period** | : | Gestation day 14 through 21 days of lactation |
| **Frequency of treatment** | : | Daily |
| **Duration of test** | : | Through lactation day 21 |
| **Doses** | : | 12, 24, and 48 mg/kg b.w. (equivalent to 5.4, 10.8, or 21.8 mg Co/kg b.w.) |
| **Control group** | : | Yes |
| **NOAEL maternal tox.** | : | Not determined (no maternal data reported) |
| **NOAEL teratogen.** | : | Malformations not observed |
| **Other** | : | |
| **Other** | : | |
| **Other** | : | |
| **Year** | : | 1985 |
| **GLP** | : | No |
| **Test substance** | : | Cobalt chloride |
| **Method** | : | |
| **Method detail** | : | Cobalt chloride was administered to three groups of 15 pregnant rats from gestation day 14 through the 21$^{st}$ day of lactation. Pups were weighed and examined for signs of toxicity on days 1, 4, and 21 of lactation, and were sacrificed on day 21. Macroscopic examinations were made of the heart, lungs, spleen, liver, and kidneys following sacrifice. Clinical chemistry parameters were also measured. |
| **Result** | : | There was significant mortality of pups in the highest dose group and fewer litters produced at all dose levels. In addition, pups showed stunted growth (weight and length) at all dose levels. Relative weights of the liver (males and females) and spleen (females only) were reduced by cobalt exposure, but did not show a dose-related trend. Blood analysis and clinical chemistry showed no treatment related differences. No external malformations were observed in pups. Data from previous studies by the authors suggests that the upper two doses levels were maternally toxic, therefore, the results observed may have been indirectly due, at least in part, to effects on the mothers, rather than direct effects on the fetuses. |
| **Remark** | : | |
| **Reliability** | : | 2 (Reliable with restrictions): comparable to guideline study with adequate documentation. |
| **Reference** | : | Domingo, J.L., J.L. Paternain, J.M. Llobet, and J. Corbella. 1985. Effects of cobalt on postnatal development and late gestation in rats upon oral administration. Rev. Esp. Fisiol., 41:293-298. |

| | | |
|---|---|---|
| **Type** | : | Teratogenicity |
| **Guideline/method** | : | Not specified |
| **Species** | : | Rat |
| **Strain** | : | Sprague-Dawley |
| **Sex** | : | Female |
| **Route of admin.** | : | Oral gavage |
| **Exposure period** | : | Day 6 to 15 of gestation |
| **Frequency of treatment** | : | Daily |
| **Duration of test** | : | To day 20 of gestation |
| **Doses** | : | 25, 50, or 100 mg/kg (equivalent to 6.2, 12.4, and 24.8 mg Co/kg b.w.) |
| **Control group** | : | Yes |

| | | |
|---|---|---|
| **NOAEL maternal tox.** | : | Not determined (effects on weight gain seen at lowest dose) |
| **NOAEL teratogen.** | : | 24.8 mg Co/kg b.w. |
| **Other** | : | NOAEL for maternal hematology was 12.4 mg Co/kg b.w. |
| **Other** | : | |
| **Other** | : | |
| **Year** | : | 1998 |
| **GLP** | : | |
| **Test substance** | : | Cobalt chloride hexahydrate ($CoCl_2 \cdot 6H_20$) |
| **Method** | : | |
| **Method detail** | : | Pregnant females (20 per group) were dosed daily with cobalt chloride hexahydrate in distilled water during gestation days 6 to 15. Maternal body weights were recorded on days 0, 6, 9, 12, 16, and 19 of gestation. Individual food consumption was recorded for the following intervals: days 0-6, 6-9, 9-12, 12-16 and 16-19. Detailed physical examinations for signs of toxicity were performed at the same time that weights were recorded. On day 20 of gestation, dams were weighed, then sacrificed. Blood samples were collected for hematological analyses. After exsanguinations, the uterine horns were opened, examinations made and the following recorded: number of corpora lutea, total implantations, number of live and dead fetuses number of resorptions, average fetus body weight, number of stunted fetuses, fetal body length, and fetal tail length. Fetuses were also fixed, stained and examined for skeletal abnormalities. |
| **Result** | : | Maternal effects included significant reductions in weight gain and food consumption, particularly at the 24.8 mg Co/kg dose level, although effects on weight gain were found at all dose levels. Hematological parameters (e.g., hematocrit, hemoglobin content) were significantly increased in the highest dose group. No treatment-related changes were observed in the number of corpora lutea, total implants, resorptions, number of live and dead fetuses per litter, fetal size parameters, or fetal sex distribution data. Increased incidences of stunted fetuses per litter (those under two-thirds of the average fetus body weight) were seen in the two highest dose groups; however, the increases were not statistically significant. Examination of fetuses for gross external abnormalities, skeletal malformations, and ossification variations produced negative findings, indicating that cobalt doses as high as 24.8 mg Co/kg do not produce teratogenicity or significant fetotoxicity in the rat. |
| **Remark** | : | A lack of teratogenicity in the golden hamster has also been reported (Ferm, V.H. 1972. Adv. Teratol., 6:51-75. |
| **Reliability** | : | 2 (Reliable with restrictions): comparable to guideline study with adequate documentation. |
| **Reference** | : | Paternain, J.L., J.L. Domingo, and J. Corbella. 1988. Developmental toxicity of cobalt in the rat. J. Toxicol. Environ. Health, 24:193-200. |

| | | |
|---|---|---|
| **Type** | : | Developmental toxicity |
| **Guideline/method** | : | Chernoff/Kavlock developmental toxicity screen |
| **Species** | : | Mouse |
| **Strain** | : | ICR/SIM |
| **Sex** | : | Female |
| **Route of admin.** | : | Oral intubation |
| **Exposure period** | : | Gestation days 8 through 12 |
| **Frequency of treatment** | : | Daily |
| **Duration of test** | : | Through postnatal day 3 |
| **Dose** | : | 180 mg/kg/day (equivalent to 81.7 mg Co/kg) |
| **Control group** | : | Yes |
| **NOAEL maternal tox.** | : | Not determined |
| **NOAEL teratogen.** | : | 180 mg/kg/day (equivalent to 81.7 mg Co/kg) |
| **Other** | : | |

| | | |
|---|---|---|
| **Other** | : | |
| **Other** | : | |
| **Year** | : | 1986 |
| **GLP** | : | |
| **Test substance** | : | Cobalt chloride |
| **Method** | : | Chernoff, N. and R.J. Kavlock. 1982. J. Toxicol. Environ. Health, 10:541-550. |
| **Method detail** | : | The screening test was carried out with a single minimally dose that was expected to result in significant maternal weight reduction, up to 10% mortality, or other clinical sings of overt toxicity. Treatment was by oral intubation on days 8 through 12 of gestation. Mice were allowed to deliver, and neonates examined, counted, and weighed on the day of birth (day 1) and day 3. Dead neonates were recovered from the nest and examined for abnormalities. |
| **Result** | : | The average maternal weight gain was significantly affected by cobalt treatment as desired in the protocol. Despite this, there was no effect of cobalt on litter size, percent survival of neonates on days 1-3, or average neonatal weight. |
| **Remark** | : | Results are in agreement with those seen in the rat, although another researcher has reported that injections of cobalt chloride to pregnant mice can lead to interference of skeletal ossification in fetuses (Wide, M. 1984. Environ. Res., 33:47-53). |
| **Reliability** | : | 2 (Reliable with restrictions): comparable to guideline study with adequate documentation. |
| **Reference** | : | Seidenberg, J.M. D.G. Anderson, and R.A. Becker. 1986. Validation of an in vivo developmental toxicity screen in the mouse. Teratog. Carcinog. Mutagen., 6:361-374. |

### 5.8.3 TOXICITY TO REPRODUCTION

| | | |
|---|---|---|
| **Type** | : | Male reproduction |
| **Guideline/method** | : | Not specified |
| **In vitro/in vivo** | : | In vivo |
| **Species** | : | Mouse |
| **Strain** | : | CD-1 |
| **Sex** | : | Male |
| **Route of admin.** | : | Drinking water |
| **Exposure period** | : | 12 weeks (dose-response study); 13 weeks (time course study) |
| **Frequency of treatment** | : | Continuous |
| **Duration of test** | : | 12 weeks (dose-response study); 33 weeks (time course study) |
| **Doses** | : | 10, 200, or 400 ppm in the dose-response study (equivalent to a daily intake of 23.0, 42.0, or 72.1 mg Co/kg b.w.); 400 ppm in the time course study (equivalent to a daily intake of 58.9 mg Co/kg b.w.) |
| **Control group** | : | Yes |
| **Year** | : | 1988 |
| **GLP** | : | No |
| **Test substance** | : | Cobalt chloride hexahydrate ($CoCl_2 \cdot 6H_20$) |
| **Method** | : | |
| **Method detail** | : | In the dose-response study, males (5 per dose) were evaluated after 12 weeks of exposure for testicular weight, epididymal sperm concentration, sperm motility, sperm fertilizing ability (fertility), prostatic weight, seminal vesicle weight, and serum levels of testosterone. In the time course study, males (5 per dose and time point) were evaluated after 7, 9, 11, or 13 weeks of exposure for most of these same parameters. In addition, fertility of the males was evaluated at regular intervals up to 20 weeks after cessation of cobalt treatment in the drinking water. |
| **Result** | : | Cobalt exposure affected male reproductive parameters in a time- and |

dose-dependent manner. There was a significant decrease in testicular weight and epididymal sperm concentration after 11-13 weeks of exposure at all dose levels. Sperm motility and fertility were significantly depressed in the highest exposure groups. After cessation of exposure, some recovery was seen in fertility over time; however, indices remained significantly depressed through study termination (20 weeks after cessation). Parallel studies with acute cobalt chloride exposures (i.p injections of 200 µmoles/kg for 3 consecutive days) did not result in significant changes in male reproductive parameters, although transient affects on fertility were observed.

**Remark** : Histopathology studies of testes from mice treated with the same general exposure regimen as in this study (i.e., 400 ppm in drinking water for 13 weeks) showed a reproducible, sequential pattern of seminiferous tubule degeneration (Anderson, M.B. et al., 1992. Reprod. Toxicol., 6:41-50). Results of this study are highly consistent with others in which testicular degeneration and atrophy have been reported in rats exposed to 13.2 to 30.2 mg Co/kg/day as cobalt chloride for 2-3 months in the diet or drinking water (ATSDR Sept 2001 Draft).

**Reliability** : 2 (Reliable with restrictions): comparable to guideline study with adequate documentation.

**Reference** : Pedigo, N.G., W.J. George, and M.B. Anderson. 1988. Effects of acute and chronic exposure to cobalt on male reproduction in mice. Reprod. Toxicol., 2:45-53.

**Type** : Male reproduction
**Guideline/method** : Not specified
**In vitro/in vivo** : In vivo
**Species** : Rat
**Strain** : Sprague-Dawley
**Sex** : Male
**Route of admin.** : Diet
**Exposure period** : 98 d
**Frequency of treatment** : Continuous in diet
**Duration of test** : Up to 98 d
**Doses** : 265 ppm in diet (equivalent to 20 mg Co/kg b.w. at test initiation)
**Control group** : Yes
**Year** : 1985
**GLP** : No
**Test substance** : Cobalt chloride hexahydrate ($CoCl_2 \cdot 6H_20$)
**Method** :
**Method detail** : Three rats from the control and treatment groups were sacrificed on days 1, 2, 7, 14, 21, 28, 35, 42, 56, 63, 70, 84, and 98. Tissue specimens from the testes, cauda epididymus, and seminal vesicles were fixed and later examined.

**Result** : Dietary cobalt exposure induced consistent degenerative and necrotic lesions in the seminiferous tubules of rats. Cyanosis and engorgement of testicular vasculature on day 35 and thereafter was followed on day 70 by degenerative and necrotic changes in the germinal epithelium and Sertoli cells. Findings indicate that cobalt readily crosses the blood-testes barrier.

**Remark** : Results are consistent with those of Nation et al. (1983), who found significant testicular atrophy in rats exposed chronically to 20 mg Co/kg in the diet (Nation, J.R. et al., 1983. Neurobehav. Toxicol. Teratol., 5:9-15).

**Reliability** : 2 (Reliable with restrictions): comparable to guideline study with adequate documentation.

**Reference** : Corrier, D.E., H.H. Mollenhauer, D.E. Clark, M.F. Hare, and M.H. Elissalde. 1985. Testicular degeneration and necrosis induced by dietary cobalt. Vet. Pathol., 22:610-616.

## 6.0 OTHER INFORMATION

### 6.1 CARCINOGENICITY

The US National Toxicology Program does not recognize cobalt as a human carcinogen, but IARC has classified cobalt and cobalt compounds as possibly carcinogenic to humans (Class 2B) based on sufficient evidence that cobalt metal powder and cobaltous oxide are carcinogenic in animals (Barceloux 1999, ATSDR Sept 2001 Draft). “No studies were located regarding carcinogenic effects in animals after oral exposure to stable [non-radioactive] cobalt.” (ATSDR Sept 2001 Draft).

## 1. General Information

**ID** 6865-35-6

**Date** July 1, 2008

# Appendix A: Cobalt Stearate

Prepared by the Metal Carboxylates Coalition

201-16741D



### 1.0 SUBSTANCE INFORMATION

| | | |
|---|---|---|
| **Generic Name** | : | Cobalt Stearate |
| **Chemical Name** | : | |
| **CAS Registry No.** | : | 13586-84-0 |
| **Component CAS Nos.** | : | |
| **EINECS No.** | : | |
| **Structural Formula** | : | $Co(C_{18}H_{35}O_2)_2$ |
| **Molecular Weight** | : | 625.9 |
| **Synonyms and Tradenames** | : | Octadecanoic acid, cobalt salt; stearic acid, cobalt salt |

### 2.1 MELTING POINT

| | | |
|---|---|---|
| **Type** | : | Melting Point/Melting Range Determination |
| **Guideline/method** | : | OECD 102; EPA OPPTS 830.7200 |
| **Value** | : | 45.1º to 79.3°C |
| **Decomposition** | : | Starts at 177°C |
| **Sublimation** | : | |
| **Year** | : | 2003 |
| **GLP** | : | Yes |
| **Test substance** | : | Cobalt stearate, batch H08 M23, 9.41% cobalt, purple solid, provided by Alfa Aesar |
| **Method** | : | OECD 102, Melting Point/Melting Range, July 1995; EPA Product Properties Test Guidelines, OPPTS 830.7200, Melting Point/Melting Range, March 1998 |
| **Method detail** | : | A differential scanning colorimeter (DSC 821, Fa, Mettler Toledo) was used to determine the melting point/range (the temperature or temperature range at which phase transition from solid to liquid state occurs). A preliminary test was conducted at a heating rate of 20 K/min from 25ºC to 400ºC and the quantities of heat absorbed or released were measured and recorded. The weight and appearance of the sample were recorded before and after the test. Based upon the preliminary test results, two definitive runs were made at a heating rate of 5 K/min from 25ºC to 120ºC to determine the onset and end of the endothermic reaction. |
| **Result** | : | The melting range was determined from the mean of two definitive runs to be between 45.1ºC and 79.3ºC (318.3 K and 340.7 K) |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Acid:** The melting point reported for stearic acid is 69 - 70°C (Appendix D).<br>**Metal:** The melting point reported for cobalt chloride is 735ºC (Appendix C). |
| **Reliability** | : | [1] Reliable without restriction |
| **Reference** | : | Tognucci, A., 2003. Determination of the Melting Point/Melting Range of Cobalt Stearate, RCC Study No. 849123, conducted for the Metal Carboxylates Coalition by RCC Ltd., Switzerland. |

### 2.2 BOILING POINT

| | | |
|---|---|---|
| **Type** | : | Boiling Point/Boiling Range Determination |
| **Guideline/method** | : | OECD 103; EPA OPPTS 830.7220 |
| **Value** | : | Decomposition observed before boiling could occur |
| **Decomposition** | : | Starts at 177° |
| **Year** | : | 2003 |
| **GLP** | : | Yes |
| **Test substance** | : | Cobalt stearate, batch H08 M23, 9.41% cobalt, purple solid, provided by Alfa Aesar |
| **Method** | : | OECD 103, Boiling Point, 1995; EPA Product Properties Test Guidelines, OPPTS 830.7220, Boiling Point/Boiling Range, August 1996 |
| **Method detail** | : | A differential scanning colorimeter (DSC 821, Fa, Mettler Toledo) was used to determine the boiling point/range (the temperature or temperature range at which the vapor pressure of a liquid is the same as the standard pressure). A preliminary test was conducted at a heating rate of 20 K/min from 25ºC to 400ºC and the quantities of heat absorbed or released were measured and recorded. The weight and appearance of the sample were recorded before and after the test. A definitive run was made at a heating rate of 5 K/min from 130ºC to 300ºC; however no peak was observed from which boiling could be deduced. |
| **Result** | : | The boiling point was not observed because the test material decomposed prior to boiling. |

| | | |
|---|---|---|
| **Remark** | : | **Supporting data for dissociation products:**<br>**Acid:** The reported boiling point for stearic acid is 383 °C (Appendix D).<br>**Metal:** The reported boiling point for cobalt chloride is 1,049ºC (Appendix C). |
| **Reliability** | : | [1] Reliable without restriction |
| **Reference** | : | Tognucci, A., 2003. Determination of the Boiling Point/Boiling Range of Cobalt Stearate, RCC Study No. 849124, conducted for the Metal Carboxylates Coalition by RCC Ltd., Switzerland. |

### 2.3 DENSITY

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Value** | : | 1.035 |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Acid:** Reported value for stearic acid is 0.9408 at 20°C (HSDB 8/16/02).<br>**Metal:** Reported value for cobalt chloride is 3.367 at 25ºC (Appendix C). |
| **Reliability** | : | |
| **Reference** | | Certificate of Analysis for Cobalt Stearate, Lot Number H08M23, 9.41% cobalt, prepared by Alfa Aesar, Ward Hill, MA. |

### 2.4 VAPOR PRESSURE

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Value** | : | hPa at °C |
| **Decomposition** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Acid**: The reported vapor pressure for stearic acid is 1.33 hPa at 173.7°C (Appendix D). |
| **Reliability** | : | |
| **Reference** | : | |

### 2.5 PARTITION COEFFICIENT

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Partition coefficient** | : | |
| **Log Pow** | : | at °C |
| **pH value** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |

| | | |
|---|---|---|
| **Result** | : | |
| **Remark** | : | Determination of octanol/water partition coefficient (Kow) is inappropriate for metal carboxylate compounds such as cobalt stearate. Kow is determined on unionized, undissociated chemicals. Due to the complex water chemistry of cobalt stearate, and the presence of dissociated ionized constituents, measuring Kow would be extremely difficult if not impossible, and would not provide meaningful data. A worst-case estimate of log Kow, calculated for the salt ion pairs using EPIWIN, is 15.1; however, this value most probably over-predicts the potential for bioaccumulation of cobalt stearate under environmentally-relevant conditions.<br>**Supporting data for dissociation products:**<br>**Acid:** Log Kow for stearic acid is reported as 8.42 (Appendix D).<br>**Metal:** not applicable (ionizes in water) |
| **Reliability** | : | |
| **Reference** | : | |

### 2.6.1 SOLUBILITY IN WATER

| | | |
|---|---|---|
| **Type** | : | Water Solubility Determination |
| **Guideline/method** | : | OECD 105; EPA OPPTS 830.7840 |
| **Value** | : | 6.4 mg/L at 20ºC |
| **pH value** | : | |
| **concentration** | : | at °C |
| **Temperature effects** | : | |
| **Examine different pol.** | : | |
| **PKa** | : | at °C |
| **Description** | : | |
| **Stable** | : | |
| **Deg. product** | : | |
| **Year** | : | 2003 |
| **GLP** | : | Yes |
| **Test substance** | : | Cobalt stearate, Batch H08 M23, 9.41% cobalt, purple solid, provided by Alfa Aesar |
| **Deg. products CAS#** | : | |
| **Method** | : | OECD 105, Water Solubility, 1995; EPA Product Properties Test Guidelines, OPPTS 830.7840, Water Solubility: Column Elution Method, Shake Flask Method, 1998. |
| **Method detail** | : | The results of a preliminary test using a simplified flask method indicated the solubility was below 10 mg/L; therefore, the column elution method was used in the definitive test. The column was prepared by adding 6.05 g of glass beads into a flask, adding 0.120 g ground test material and mixing for 5 minutes. This was then poured into the elution column which was subsequently filled with water and equilibrated for approximately 2 hours. A circulation pump was used to elute the cobalt stearate from the carrier material. Temperature was 20ºC. The flow rate was 0.52 mL/min for 71 hours, followed by a period of 24 hours at 0.26 mL/min. The apparatus was run until equilibration of the saturation column was obtained, defined by at least five successive samples whose concentrations do not differ more than 30%. The column eluate was sampled at 1 hour intervals to determine the concentration of cobalt, using atomic absorption spectroscopy. |
| **Result** | : | Based on the results of 12 samples, the cobalt solubility was 0.6 mg/L (SD ± 0 mg/L) which corresponds to a water solubility of cobalt stearate of 6.4 mg/L (calculated based on cobalt content of 9.41%). The pH during the test ranged from 7.04 to 7.98. |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Acid:** The reported water solubility for stearic acid is 0.568 mg/L at 25 °C (Appendix D). |

**Metal:** The reported water solubility for cobalt chloride is 450 g/L at 7ºC (Appendix C).

**Reliability** : [1] Reliable without restriction

**Reference** : Tognucci, A., 2003. Determination of the Water Solubility of Cobalt Stearate, RCC Study No. 849126, conducted for the Metal Carboxylates Coalition by RCC Ltd., Switzerland.

## 2.7 FLASH POINT

**Type** :

**Guideline/method** :

**Value** : °C

**Year** :

**GLP** :

**Test substance** :

**Method** :

**Method detail** :

**Result** :

**Remark** :

**Reliability** :

**Reference** :

### 3.1.1 PHOTODEGRADATION

| | | |
|---|---|---|
| **Type** | | |
| **Guideline/method** | : | |
| **Light source** | : | |
| **Light spectrum** | : | |
| **Relative intensity** | : | based on |
| **Spectrum of substance** | : | lambda (max, >295nm) : |
| | | epsilon (max) : |
| | | epsilon (295) : |
| **Conc. of substance** | : | at °C |
| **DIRECT PHOTOLYSIS** | | |
| **Halflife (t1/2)** | : | |
| **Degradation** | : | % after |
| **Quantum yield** | : | |
| **INDIRECT PHOTOLYSIS** | | |
| **Sensitizer** | : | |
| **Conc. of sensitizer** | : | |
| **Rate constant** | : | |
| **Degradation** | : | |
| **Deg. product** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Deg. products CAS#** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Acid**: Half life of 0.5 days for stearic acid, calculated using AopWin v1.91 (Appendix D).<br>**Metal:** not applicable, metal does not degrade |
| **Reliability** | : | |
| **Reference** | : | |

### 3.1.2 DISSOCIATION

| | | |
|---|---|---|
| **Type** | : | Dissociation constant determination |
| **Guideline/method** | : | OECD 112 |
| **pKa** | : | 7.50 at 20°C |
| **Year** | : | 2002 |
| **GLP** | : | Yes |
| **Test substance** | : | Cobalt stearate, lot number F26L13, received from Alfa Aesar. Dark pellets, purity of 9.6% cobalt. |
| **Approximate water solubility** | : | 0.17 mg/L, determined by Inductively Coupled Plasma Atomic Emission Spectrometry during preliminary study |
| **Method** | : | OECD Guideline 112, Dissociation Constants in Water |
| **Method detail** | : | Three replicate samples of cobalt stearate were prepared at a nominal concentration of 0.10 mg/L by fortification of 100 mL of degassed water (ASTM Type II) with a 0.10 mg/mL stock solution of the test substance in tetrahydrofuran. Each sample was titrated against 0.00025 N sodium hydroxide while maintained at a test temperature of 20±1°C. At least 10 incremental additions were made before the equivalence point and the titration was carried past the equivalence point. Values of pK were calculated for a minimum of 10 points on the titration curve. Phosphoric acid and 4-nitrophenol were used as reference substances. |
| **Result** | : | Mean (N = 3) pKa value was 7.50 (SD = 0.0356) at 20°C |

| | | |
|---|---|---|
| **Remark** | : | The results indicate that dissociation of the test substance will occur at environmentally-relevant pH values (approximately neutral) and at physiologically-relevant pH values (approximately 1.2). |
| **Reliability** | : | [1] Reliable without restriction. |
| **Reference** | : | Lezotte, F.J. and W.B. Nixon, 2002. Determination of the dissociation constant of cobalt stearate, Wildlife International, Ltd. Study No. 534C-113, conducted for the Metal Carboxylates Coalition. |

### 3.2.1 MONITORING DATA

| | | |
|---|---|---|
| **Type of measurement** | : | |
| **Media** | : | |
| **Concentration** | : | |
| **Substance measured** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | |
| **Reliability** | : | |
| **Reference** | : | |

### 3.3.1 TRANSPORT (FUGACITY)

| | | |
|---|---|---|
| **Type** | : | |
| **Media** | : | |
| **Air** | : | % (Fugacity Model Level I) |
| **Water** | : | % (Fugacity Model Level I) |
| **Soil** | : | % (Fugacity Model Level I) |
| **Biota** | : | % (Fugacity Model Level II/III) |
| **Soil** | : | % (Fugacity Model Level II/III) |
| **Year** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Acid**: Using EPIWIN v. 3.11, the Level III fugacity model predicts distribution of stearic acid primarily to sediment (63.3%), followed by soil (28.9%), water (7.19%) and air (<1%). See Appendix D. |
| **Reliability** | : | |
| **Reference** | : | |

### 3.5 BIODEGRADATION

| | | |
|---|---|---|
| **Type** | : | $CO_2$ Evolution Test (Ready Biodegradability) |
| **Guideline/method** | : | OECD 301B |
| **Inoculum** | : | Activated Sludge |
| **Concentration** | : | 30 mg/L related to activated sludge concentration<br>3.0 mL related to fresh soil filtrate |
| **Contact time** | : | 28 Days |
| **Degradation** | : | 8.81 (±) % after 28 day(s) |
| **Result** | : | |
| **Kinetic of test subst.** | : | % (specify time and % degradation)<br>%<br>%<br>% |

| | | |
|---|---|---|
| | | % |
| **Control substance** | : | |
| **Kinetic** | : | 73.62 % by day 10<br>91.98 % by day 28 |
| **Deg. product** | : | |
| **Year** | : | 2006 |
| **GLP** | : | Yes |
| **Test substance** | : | Cobalt stearate |
| **Deg. products CAS#** | : | 1002-88-6, 13586-84-0 |
| **Method** | : | OECD Method 301B |
| **Method detail** | : | |
| **Result** | : | The mean cumulative net $CO_2$ evolved (amount of biodegradation) from the aqueous medium fortified with Co stearate at 10 mg C/L was 8.81% of the theoretical amount (based on inorganic carbon measurements). The toxicity control evolved 49.96% of the theoretical carbon available for biodegradation, which indicates that Co stearate was not inhibitory to the biodegradation of the reference compound.<br><br>The cumulative net $CO_2$ evolved from the sodium benzoate procedural control was 73.62% of theoretical by day 10 and 91.98% of theoretical by day 28, thus exceeding the "pass" criteria of the test (reaching 60% or greater $CO_2$ evolution within 28 days and within a 10-day window of reaching 10% biodegradation). This rapid biodegradation of sodium benzoate confirmed the presence of an active microbial population and system integrity.<br><br>Based on the $CO_2$ analysis results from this study, Co stearate, was not "readily biodegradable" according to the OECD 301B guideline. The rapid degradation of the reference substance confirmed the presence of an acceptable microbial community and confirmed system integrity. The cobalt salt did not inhibit microbial degradation of the reference compound sodium benzoate. |
| **Remark** | : | **CAS No.:** The sample used in this testing is representative of two CAS Nos. 1002-88-6 and 13586-84-0. Research by CAS staff to define both CAS Nos and comparative IR spectra confirm that the sample is representative of both CAS Nos<br><br>**Supporting data for dissociation products:**<br>**Acid**: Stearic acid is readily biodegradable in activated sludge under aerobic conditions: 77% degraded in 28 days in BOD test; 95% in 21 days in Sturm $CO_2$ evolution test; reported half-life of 3 -10 days in additional studies (Appendix D).<br>**Metal:** not applicable, metal does not degrade. |
| **Reliability** | : | [1]Reliable without restriction |
| **Reference** | : | Cobalt Stearate (Co Stearate) - Determination of the Biodegradability of a Test Substance Based on OECD Method 301B ($CO_2$ Evolution Test). (2006) Conducted by Springborn Smithers Laboratories for the Metal Carboxylates Coalition. Study No. 13865.6111 |

### 3.7 BIOCONCENTRATION

| | | | |
|---|---|---|---|
| **Type** | : | | |
| **Guideline/method** | : | | |
| **Species** | : | | |
| **Exposure period** | : | at | °C |
| **Concentration** | : | | |
| **BCF** | : | | |
| **Elimination** | : | | |
| **Year** | : | | |
| **GLP** | : | | |
| **Test substance** | : | | |
| **Method** | : | | |
| **Method detail** | : | | |
| **Result** | : | | |
| **Remark** | : | | |
| **Reliability** | : | | |
| **Reference** | : | | |

## 4.1 ACUTE TOXICITY TO FISH

| | | |
|---|---|---|
| **Type** | : | Acute toxcicity to fish under flow-through conditions |
| **Guideline/method** | : | OECD 203 |
| **Species** | : | Rainbow trout (*Oncorhynchus mykiss*) |
| **Exposure period** | : | 96-h |
| **NOEC** | : | 6.2 mg cobalt stearate/L |
| **LC0** | : | |
| **LC50** | : | > 6.2 mg/L (0.58 mg Co/L) |
| **LC100** | : | |
| **Other** | : | |
| **Other** | : | |
| **Limit test** | : | |
| **Analytical monitoring** | : | Concentrations in test solutions were: 0.23, 0.72, 1.3, 3.0, and 6.2 mg cobalt stearate/L based on measured concentrations of Co (0.021, 0.067, 0.12, 0.28, and 0.58 mg Co/L). Water concentrations of Co were measured 0,48, and 96 hours by Inductively Coupled Plasma Mass Spectrometry (ICP-MS) |
| **Year** | : | 2007 |
| **GLP** | : | Yes |
| **Test substance** | : | Cobalt stearate, Lot no. 19731 MI, CAS No. 1002-88-6, reported as a putiry of 92.9% (9.36% Co) as received from Aldrich Chemical. This sample is also representative of CAS No. 13586-84-0 (see remarks section). |
| **Method** | : | |
| **Method detail** | | |
| **Result** | : | The NOEC was 6.2 mg cobalt stearate/Land the LC50 is > 6.2 mg cobalt stearate/L |
| **Remark** | : | **CAS No.:** The sample used in this testing is representative of two CAS Nos. 1002-88-6 and 13586-84-0. Research by CAS staff to define both CAS Nos and comparative IR spectra confirm that the sample is representative of both CAS Nos<br>**Supporting information for dissociation products:**<br>**Acid:** For stearic acid, the LT50 was > 96 hours at 12 mg/L for *Oncorhynchus kisutch* (Appendix D).<br>**Metal:** For cobalt chloride, the 96-h LC50 was 1.41 mg Co/L for the highly sensitive rainbow trout, *Onchorynchus mykiss*. Toxicity to other fish species ranges from LC50 values of 22 – 333 mg Co/L. Toxicity is dependent upon water hardness (Appendix C). |
| **Reliability** | : | [1] without restriction |
| **Reference** | : | Cobalt Stearate- Acute toxicity to rainbow trout (*Onchorhynchus mykiss*) under flow-through conditions, |

## 4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

| | | |
|---|---|---|
| **Type** | | Acute toxicity to aquatic invertebrates under flow-through conditions. |
| **Guideline/method** | : | OECD Guideline 202 |
| **Species** | : | |
| **Exposure period** | : | 48 h |
| **NOEC** | : | |
| **EC0** | : | |
| **EC50** | : | |
| **EC100** | : | |
| **Other** | : | |
| **Other** | : | |
| **Other** | : | |
| **Limit test** | : | |

| | | |
|---|---|---|
| **Analytical monitoring** | : | Yes Water concentrations of Co were measured 0,48, and 96 hours by Inductively Coupled Plasma Mass Spectrometry (ICP-MS) |
| **Year** | : | 2006 |
| **GLP** | : | yes |
| **Test substance** | : | Cobalt stearate, Lot no. 19731 MI, CAS No. 1002-88-6, reported as a purity of 92.9% (9.36% Co) as received from Aldrich Chemical. This sample is also representative of CAS No. 13586-84-0 (see remarks section). |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | Since no concentration tested resulted in ≥ 50% immobilization, |
| **Remark** | : | **CAS No.:** The sample used in this testing is representative of two CAS Nos. 1002-88-6 and 13586-84-0. Research by CAS staff to define both CAS Nos and comparative IR spectra confirm that the sample is representative of both CAS Nos. **Supporting information for dissociation products: Metal:** For cobalt chloride, the 48-h EC50 for *Daphnia magna* was 1.52 mg Co/L. In other studies, and with other species, 48-h LC50 values ranged from 1.52 – 5.5 mg Co/L. (Appendix C). |
| **Reliability** | : | [1] without restriction |
| **Reference** | : | Cobalt Stearate- Acute toxicity to Water Fleas (*Daphnia magna*) under flow-through conditions, |

### 4.3 TOXICITY TO AQUATIC PLANTS (E.G., ALGAE)

| | | |
|---|---|---|
| **Type** | : | Algal Toxicity |
| **Guideline/method** | : | OECD 201 |
| **Species** | : | |
| **Endpoint** | : | Mortality and growth |
| **Exposure period** | : | 72 h |
| **NOEC** | : | 0.49 mg/L yield and 1.8 mg/L for growth rate |
| **LOEC** | : | |
| **EC0** | : | |
| **EC10** | : | |
| **EC50** | : | 1.2 mg/L (0.12 mg Co/L) Yield; 3.2 mg/L (0.30 mg Co/L) Growth rate |
| **Other** | : | |
| **Other** | : | |
| **Limit test** | : | |
| **Analytical monitoring** | : | Yes: Nominal: |
| **Year** | : | 2006 |
| **GLP** | : | yes |
| **Test substance** | : | Cobalt stearate, Lot no. 19731 MI, CAS No. 1002-88-6, reported as a putiry of 92.9% (9.36% Co) as received from Aldrich Chemical. This sample is also representative of CAS No. 13586-84-0 (see remarks section). |
| **Method** | : | OECD 201 |
| **Method detail** | : | |
| **Result** | : | |

**Effect and NOEC values for cobalt stearate from results (yield and growth rate) after 72 hours of exposure with *Pseudokirchneriella subcapitata*.**

| Yield | Ey10 | Ey20 | Ey50 | NOEC |
|---|---|---|---|---|
| EC value (mg/L): | 0.59 | 0.72 | 1.2 | 0.49 |
| 95% Confidence Intervals: | 0.53 - 0.63 | 0.67 - 0.77 | 1.2 - 1.3 | |

| Growth rate | Er10 | ErC20 | ErC50 | NOEC |
|---|---|---|---|---|
| EC value (mg/L): | 0.96 | 1.4 | 3.2 | 1.8[b] |
| 95% Confidence Intervals: | 0.90 - 1.0 | 1.3 - 1.4 | 3.0 - 3.5 | |

| | | |
|---|---|---|
| **Remark** | : | **CAS No.:** The sample used in this testing is representative of two CAS Nos. 1002-88-6 and 13586-84-0. Research by CAS staff to define both CAS Nos and comparative IR spectra confirm that the sample is representative of both CAS Nos. **Supporting information for dissociation products: Metal:** For cobalt chloride, the 96-h EC50 for *Chorella vulgaris* was 0.52 mg Co/L. Other aquatic plants were less sensitive with EC50 values from 16.9 – 23.8 mg Co/L. (Appendix C). |
| **Reliability** | : | [1] without restriction |
| **Reference** | : | Cobalt Stearate - Acute Toxicity to the Freshwater Green Alga, *Pseudokirchneriella subcapitata,* based on OECD Method 201. (2006) Conducted by Springborn Smithers Laboratories for the Metal Carboxylates Coalition. Study No. 13865.6114 |

### 4.4 CHRONIC TOXICITY TO FISH

| | |
|---|---|
| **Type** | : |
| **Guideline/method** | : |
| **Species** | : |
| **Exposure period** | : |
| **NOEC** | : |
| **LOEC** | : |
| **LC0** | : |
| **LC50** | : |
| **LC100** | : |
| **Other** | : |
| **Other** | : |
| **Limit test** | : |
| **Analytical monitoring** | : |
| **Year** | : |
| **GLP** | : |
| **Test substance** | : |
| **Method** | : |
| **Method detail** | : |
| **Result** | : |
| **Remark** | : |
| **Reliability** | : |
| **Reference** | : |

### 4.5 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

| | |
|---|---|
| **Type** | : |
| **Guideline/method** | : |
| **Species** | : |
| **Exposure period** | : |
| **NOEC** | : |
| **LOEC** | : |
| **EC0** | : |
| **EC50** | : |
| **EC100** | : |
| **Other** | : |
| **Other** | : |
| **Limit test** | : |
| **Analytical monitoring** | : |
| **Year** | : |

| | |
|---|---|
| **GLP** | : |
| **Test substance** | : |
| **Method** | : |
| **Method detail** | : |
| **Result** | : |
| **Remark** | : |
| **Reliability** | : |
| **Reference** | : |

## 5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

| | | |
|---|---|---|
| **In vitro/in vivo** | : | |
| **Type** | : | |
| **Guideline/method** | : | |
| **Species** | : | |
| **Number of animals** | : | |
| **Males** | : | |
| **Females** | : | |
| **Doses** | : | |
| **Males** | : | |
| **Females** | : | |
| **Vehicle** | : | |
| **Route of administration** | : | |
| **Exposure time** | : | |
| **Product type guidance** | : | |
| **Decision on results on acute tox. tests** | : | |
| **Adverse effects on prolonged exposure** | : | |
| **Half-lives** | : | 1st:<br>2nd:<br>3rd: |
| **Toxic behavior** | : | |
| **Deg. product** | : | |
| **Deg. products CAS#** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | **Supporting information for dissociation products:**<br>**Metal:** Absorption of cobalt in the digestive tract is influenced by the chemical form of the metal, with increasing solubility resulting in increased absorption. Approximately 13-34% of cobalt chloride, a soluble form, is absorbed in the gut of rats, but absorption in the gut may be increased in iron deficient individuals. Following oral exposure, cobalt is eliminated primarily in feces and secondarily in urine. For the more soluble forms of cobalt, e.g., cobalt chloride, 70 – 80% of the administered dose is eliminated in the feces. For absorbed cobalt, elimination is rapid primarily in the urine (Barceloux, D.G. (1999) Cobalt. Clin. Tox. 37(2):201-206). Elimination is biphasic or triphasic. The terminal phase involves a very small residual level of cobalt and has a half-life in years (Appendix C). |
| **Reliability** | : | |
| **Reference** | : | |

### 5.1.1 ACUTE ORAL TOXICITY

| | | |
|---|---|---|
| **Type** | : | Acute Toxicity study with rats – Up an Down Procedure |
| **Guideline/Method** | : | OECD #425 |
| **Species** | : | Rat |
| **Strain** | : | Crl:CD(SD) |
| **Sex** | : | Female |
| **Number of animals** | : | 5 |
| **Vehicle** | : | 0.1% Tween 80 (V/V) in 0.5% aqueous methylcellulose |
| **Doses** | : | 2000, 550 and 175 mg/kg |

| | | |
|---|---|---|
| **LD50** | : | >2000 mg/kg for female rats |
| **Year** | : | 2007 |
| **GLP** | : | Yes |
| **Test substance** | : | Co stearate (see remarks section) |
| **Method** | : | OECD, Section 4 (part 425):Acute Oral Toxicity – UP-and – Down Procedure, Guideline for Testing of Chemicals |
| **Method detail** | : | |
| **Result** | : | The oral LD50 is greater than 2000 mk/kg for female rats |
| **Remark** | : | **CAS No.:** The sample used in this testing is representative of two CAS Nos. 1002-88-6 and 13586-84-0. Research by CAS staff to define both CAS Nos and comparative IR spectra confirm that the sample is representative of both CAS Nos. |
| **Reliability** | : | [1] without restriction |
| **Reference** | : | Cobalt Stearate: Acute Oral Toxicity Study in Rats – Up and Down Procedure (2007). Conducted by Duponts Haskell Lab for the Metal Carboxylates Coalition. |

**ACUTE ORAL TOXICITY**

| | | |
|---|---|---|
| **Type** | : | Single dose |
| **Guideline/Method** | : | |
| **Species** | : | Rat |
| **Strain** | : | |
| **Sex** | : | Both male and females |
| **Number of animals** | : | Five per dose level (30 overall) |
| **Vehicle** | : | Propylene Glycol |
| **Doses** | : | 1.0, 2.0, 4.0, 8.0, 16.0, and 32.0 gm /kg |
| **LD50** | : | 9.82 gm /kg (+ 95% CI 7.45-12.95 gm /kg) |
| **Year** | : | 1977 |
| **GLP** | : | No |
| **Test substance** | : | Co Stearate |
| **Method** | : | Oral gavage |
| **Method detail** | : | Young rats 200-300 gms were randomized and dosed via oral gavage and observed for 14 days |
| **Result** | : | Observations included: lethargy, unkempt coat, diarrhea, nasal hemorrhage, and at 16.0 gm /kg loss of mototr control . In the high dose the mortalities occurred within 24 hours. At 16.0 and 8.0 gm /kg moptalities occurred between 4 and 6 days post treatment. |
| **Remark** | : | **Supporting information for dissociation products:**<br>**Acid:** Rat LD50 = 4600 mg/kg bw for stearic acid (Appendix D). Additional data: Male rats (5 males per treatment) were dosed with 0.464 to 10.0 g/kg of eutectic (triple pressed) stearic acid. The LD50 was reported as >10.0 g/kg (>10,000 mg/kg). Reference: Cosmetic, Toiletries, and Fragrance Association (1987) Cosmetic Ingredient Review, Final Report on the Safety Assessment of Oleic Acid, Lauric Acid, Palmitic Acid, Myristic Acid and Stearic Acid. J. Am. Coll. Toxicol. Vol. 6, No. 3, pp321-401. (Subsequently referred to as CTFA#3.)<br>**Metal:** Reported LD50s of cobalt chloride to rats range from 42.4 to 190 mg $CoCl_2$/kg bw (equivalent to 19.8 to 85.5 mg Co/mg bw). Toxicity of cobalt sulfate is reported to be similar to the chloride with oral LD50s for rats ranging from 123 to 161 mg/kg bw (equivalent to 46.7 to 61.2 mg Co/kg bw). For the mouse, LD50 values are 89.3 and 123 mg/kg for cobalt chloride and cobalt sulfate, respectively, which are equivalent to 40.2 and 56.7 mg/kg bw when expressed as the metal only (ATSDR Sept 2001 Draft; see Appendix C). |

| | | |
|---|---|---|
| **Reliability** | : | (2) Reliable with resptriction. Consucted prior to the the implementation of GLP. |
| **Reference** | : | Study conducted by Bio-Toxicology Laboratories, Inc. Moorestown, NJ, for The Shepherd Chemical Company Reported May 31, 1977. |

### 5.1.2 ACUTE INHALATION TOXICITY

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Species** | : | |
| **Strain** | : | |
| **Sex** | : | |
| **Number of animals** | : | |
| **Vehicle** | : | |
| **Doses** | : | |
| **Exposure time** | : | |
| **LC50** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Metal:** No acute inhalation studies have been located for cobalt chloride. |
| **Reliability** | : | |
| **Reference** | : | |

### 5.1.3 ACUTE DERMAL TOXICITY

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Species** | : | |
| **Strain** | : | |
| **Sex** | : | |
| **Number of animals** | : | |
| **Vehicle** | : | |
| **Doses** | : | |
| **LD50** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | **Supporting information for dissociation products:**<br>**Acid:** Stearic acid, 10-100 mM in olive oil was dosed intradermally in guinea pigs and rabbits which resulted in mild erythema and slight induration of skin. CTFA#3 ref 157. Stearic acid as a 20% formulations was applied at 2.0 ml/kg of product to abraded/intact sites on the backs of rabbits. After four weeks no mortaltities and slight edema and sesqumation were observed. CTFA#3 ref 163.<br>**Metal:** Increased proliferation of lymphatic cells was seen in rats, mice and guinea pigs dermally exposed to cobalt chloride, with LOAEL values ranging from 9.6 to 14.7 mg Co/kg/day (Appendix C). |

| | | |
|---|---|---|
| **Reliability** | : | |
| **Reference** | : | |

### 5.2.1 SKIN IRRITATION

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Species** | : | |
| **Strain** | : | |
| **Sex** | : | |
| **Concentration** | : | |
| **Exposure** | : | |
| **Exposure time** | : | |
| **Number of animals** | : | |
| **Vehicle** | : | |
| **Classification** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | **Supporting data for dissociation products:**<br>**Metal:** Dermatitis is a common result of dermal exposure to cobalt in humans and has been verified in a large number of studies. The dermatitis is probably caused by an allergic reaction to cobalt. (Appendix C). |
| **Reliability** | : | |
| **Reference** | : | |

### 5.2.2 EYE IRRITATION

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | |
| **Species** | : | |
| **Strain** | : | |
| **Sex** | : | |
| **Concentration** | : | |
| **Dose** | : | |
| **Exposure time** | : | |
| **Number of animals** | : | |
| **Vehicle** | : | |
| **Classification** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | **Supporting information for dissociation products:**<br>**Acid:** Stearic acid (eutectic, commercial grade) was applied to the eyes of albino rabbits following the Draise method. Results ranged from no irritation to mild conjunctival erythema in 2 rabbits subsiding by 72 hours. Stearic acid in various formulations at lower strengths showed similar results (CTFA#3). |
| **Remark** | : | |
| **Reliability** | : | |
| **Reference** | : | |

### 5.4 REPEATED DOSE TOXICITY

| | | |
|---|---|---|
| **Type** | : | See Reproduction |
| **Guideline/method** | : | |
| **Species** | : | |
| **Strain** | : | |
| **Sex** | : | |
| **Number of animals** | : | |
| **Route of admin.** | : | |
| **Exposure period** | : | |
| **Frequency of treatment** | : | |
| **Post exposure period** | : | |
| **Doses** | : | |
| **Control group** | : | |
| **NOAEL** | : | |
| **LOAEL** | : | |
| **Other** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | **Supporting information for dissociation products:**<br>**Acid:** Rats fed for 24 weeks with stearic acid (50 g/kg/day) developed foreign body type reaction in perigenital fat. Lipogranulomas were oberved to be reversible. Rats fed stearic acid (3000 ppm) for 30 weeks developed anorexia, severe pulmonary infection, and high mortality. No significant pathological lesions were observed. (CTFA#3 ref 151,152). (Appendix D).<br>**Metal:** Repeated oral dosing of rats for 150-210 days with cobalt chloride at 4 and 10 mg Co/kg indicated a LOAEL of 4 mg Co/kg, based upon increased organ weights. Eight weeks' oral exposure of rats to cobalt chloride hexahydrate indicated a LOAEL of 2.5 mg Co/kg (changes in hemoglobin and red blood cell count) and a NOAEL of 0.6 mg Co/kg. Other studies using repeated oral dosing for periods ranging from 12-16 days up to 7 months indicated LOAELs ranging from 0.5 to 30.2 mg Co/kg/day (as cobalt chloride) based upon observations such as reduced weight gain, increases in some organ weights (heart, liver and lungs); increased hematocrit, hemoglobin, and RBCs; renal tubular necrosis; and various changes on cardiac physiology (left ventricular hypertrophy, impaired ventricular function, and degeneration of myofibrils). Cardiac effects were observed in rats at LOAELs ranging from 8.4 to 12.4 mg Co/kg/day, for cobalt sulfate or cobalt chloride, with exposure periods of 3 weeks to 6 months (Appendix C). |
| **Reliability** | : | |
| **Reference** | : | |

### 5.5 GENETIC TOXICITY 'IN VITRO'

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | OECD #473 |
| **System of testing** | : | |
| **Species** | : | Chinese Hamster Ovary Cells |
| **Strain** | : | CHO-K1 cell line. |
| **Test concentrations** | : | 5 -500 ug/mL |
| **Cytotoxic concentr.** | : | $\geq$ 250 ug/mL |

**Metabolic activation** : Conducted both with and without activation. Activation system was rat S9 fraction induced with Aroclor 1254

**Year** : 2007

**GLP** : Yes

**Test substance** : Co stearate CAS#13586-84-0

**Method** : OECD #473

**Method detail** :

The test substance, Cobalt Stearate, was evaluated for its ability to induce structural chromosome aberrations *in vitro* in Chinese hamster ovary (CHO) cells in both the absence and presence of an exogenous S9 metabolic activation system (Aroclor-induced rat liver S9). Numerical aberrations were also recorded. To establish a concentration range for the chromosome aberration assay, a preliminary toxicity assay was initially conducted.

The test substance was prepared in 0.1% Tween-80 in water as this vehicle was determined to be the solvent of choice based on solubility of the test substance and compatibility with the target cells. The test substance was soluble in the vehicle at 50 mg/mL, the highest stock concentration that was prepared for use on this study. The test substance formed a cloudy dark pink suspension in the 0.1% Tween-80 in water at the highest prepared stock concentration.

In the preliminary toxicity assay, the cells were treated for 4 and 20 hours in the non-activated test conditions and for 4 hours in the S9-activated test condition. All cells were harvested
20 hours after treatment initiation. A vehicle control group was included in each test condition.

**Result** :

In the preliminary toxicity assay, the highest concentration tested was 5000 µg/mL based on the solubility of the test substance. The cells were exposed to nine concentrations of the test substance ranging from 10 to 5000 µg/mL, as well as a vehicle control. A visible precipitate was observed in the treatment medium at concentrations ≥500 µg/mL in the beginning and end of the treatment periods. The osmolality of the highest test substance concentration in medium was similar to the vehicle control both in the absence and presence of S9. The pH of the highest test substance concentration in medium was similar to the vehicle control in both the absence and presence of S9, and did not change throughout the test.

The test substance concentrations for the chromosome aberration assay were selected based on an assessment of the reduction in cell growth in the treated cultures relative to

the vehicle control. Substantial toxicity (greater than a 50% reduction in cell growth relative to the vehicle control) was observed at concentrations ≥500 µg/mL in the 4-hour non-activated test condition and at concentrations ≥250 µg/mL in the 4-hour activated and 20-hour non-activated test conditions. Based on the findings from the preliminary toxicity assay, the highest concentration chosen for the chromosome aberration assay was 500 µg/mL for all three test conditions.

In the chromosome aberration assay, the cells were treated for 4 and 20 hours in the non-activated test condition and for 4 hours in the S9-activated test condition. All cells were harvested 20 hours after treatment initiation. A vehicle control and two positive control groups were included in each test condition. The concentrations initially (trial 1) chosen for the chromosome aberration assay were 25, 50, 100, 250, and 500 µg/mL for all three test conditions. A visible precipitate was observed in the treatment medium at concentrations ≥250 µg/mL in the beginning and end of the treatment periods. Substantial toxicity was observed at concentrations ≥250 µg/mL in the 4-hour non-activated and activated test conditions (60.8% and 55.3% cell growth reduction, respectively at 250 µg/mL) and at concentrations ≥50 µg/mL in the 20-hour non-activated test condition (60.8% cell growth reduction at 50 µg/mL). A decrease in mitotic index of 56%, 97.6%, and 100% was observed at 25, 50, and 100 µg/mL, respectively in the 20-hour non-activated test condition. Because of this excessive toxicity, the assay was repeated (trial 2) for the 20-hour non-activated test condition only.

The concentrations chosen for trial 2 of the chromosome aberration assay were 5, 10, 20, 30, and 40 µg/mL for the 20-hour non-activated test condition. In trial 2, no visible precipitate was observed in the treatment medium at the beginning or end of the treatment periods at any concentration tested. Substantial toxicity was not observed at 30 µg/mL only in trial 2 (58.4% cell growth reduction). A reduction in mitotic index of 90.6% was observed at 30 µg/mL.

Selection of doses for microscopic analysis was therefore based on these dose concentration levels from trials 1 and 2.

Cytogenetic evaluations were conducted at 25, 50, and 100 µg/mL for the 4-hour non-activated and 4-hour S9-activated test conditions and at 5, 10, and 20 µg/mL for the 20-hour non-activated test condition. These concentrations were chosen

based on the toxicity data and scorability of the slides (i.e., metaphase quality, chromosome morphology, and a sufficient amount of metaphases present). The percentage of cells with structural aberrations was increased above that of the vehicle control in the 4- and 20-hour non-activated test conditions at 100 and 20 µg/mL, respectively ($p < 0.05$, Fisher's exact test). The percentage of cells with numerical aberrations was increased above that of the vehicle control in the 4-hour non-activated test condition at 50 µg/mL and in the 4-hour activated test condition at 50 and 100 µg/mL ($p < 0.05$, Fisher's exact test).

All criteria for a valid study were met. Under the conditions of this study, cobalt stearate was found to induce structural and numerical chromosome aberrations in the *in vitro* mammalian chromosome aberration test in Chinese hamster ovary cells. It was concluded that the test substance was positive in this *in vitro* test.

**Remark** : **Supporting information for dissociation products:**
**Acid:** Stearic acid was not mutagenic in *S. typhimurium* with and without metabolic activation. Stearic acid was tested for mutagenicity using the Ames test with *Salmonella typhumurium* strains TA98, TA100, TA1535, TA1537, TA1538. Spot tests were performed suing 50 mg/ml stearic acid suspensions in the distilled waster (50 µg/plate) with and without microsomal activation from hepatic S9 fractions from rats induced with Aroclor 1254 (50 µg/plate). Positive controls were 2-aminoanthracene and 4-nitro—o-phenylenediamine in dimethyl sulfoxide, 9-aminoacridinein ethanol, and sodium azide in distilled water with and without metabolic acitivation. (CTFA#3.)
**Metal**Cobalt compounds with a valence state of II, the form of cobalt released by dissociation of cobalt chloride, are reported to be generally non-mutagenic in *in vitro* bacterial assays, although weak positive responses have been observed under some conditions (Appendix C).

**Reliability** : [1] without restrictions

**Reference** : *In vitro* mammalian chromosome aberration test in Chinese hamster ovary cells (2007). Conducted by Duponts Haskell Lab for the Metal Carboxylates Coalition study number 16640-21095.

### 5.6 GENETIC TOXICITY 'IN VIVO'

**Type** :
**Guideline/method** :
**Species** :
**Strain** :
**Sex** :
**Route of admin.** :
**Exposure period** :
**Doses** :
**Year** :
**GLP** :

| | | |
|---|---|---|
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | **Supporting information for dissociation products:**<br>**Metal:** Cobalt compounds, including soluble salts, are observed to be clastogenic (cause chromosomal aberrations) in a range of mammalian assay systems. Increased micronucleus formation was observed following i.p. injection of 12.4 and 22.3 mg Co/kg (as cobalt chloride), but not after injection of 6.19 mg Co/kg (NOEL). In the mouse micronucleus test, a dose-dependent increase in the frequency of micronucleated polychromatic erythrocytes was observed with i.p. exposure to cobalt chloride hexahydrate (Appendix C). |
| **Reliability** | : | |
| **Reference** | : | |

### 5.8.2 DEVELOPMENTAL TOXICITY

| | | |
|---|---|---|
| **Type** | : | See Reproduction |
| **Guideline/method** | : | |
| **Species** | : | |
| **Strain** | : | |
| **Sex** | : | |
| **Route of admin.** | : | |
| **Exposure period** | : | |
| **Frequency of treatment** | : | |
| **Duration of test** | : | |
| **Doses** | : | |
| **Control group** | : | |
| **NOAEL maternal tox.** | : | |
| **NOAEL teratogen.** | : | |
| **Other** | : | |
| **Other** | : | |
| **Other** | : | |
| **Year** | : | |
| **GLP** | : | |
| **Test substance** | : | |
| **Method** | : | |
| **Method detail** | : | |
| **Result** | : | |
| **Remark** | : | **Supporting information for dissociation products:**<br>**Metal:** In a developmental toxicity study with cobalt chloride exposure (5.4 to 21.8 mg Co/kg/day) in rats from gestation day 14 to lactation day 21, stunted pup growth was seen at all dose levels. However, maternal toxicity was observed in conjunction with effects on the offspring. This growth effect was considered to be a secondary or indirect effect rather than a direct effect of cobalt on the fetus. No teratogenic effects were observed. Another study in rats provided a NOAEL of 24.8 mg Co/kg/day for cobalt chloride exposure from gestation days 6-15. In a screening study, no effects were observed on fetal growth or survival in mice exposed to 81.7 mg Co/kg/day as cobalt chloride during gestation days 8-12 (Appendix C). |
| **Reliability** | : | |
| **Reference** | : | |

### 5.8.3 TOXICITY TO REPRODUCTION

| | | |
|---|---|---|
| **Type** | : | |
| **Guideline/method** | : | OECD 422 |
| **In vitro/in vivo** | : | *in vivo* |
| **Species** | : | Rat |
| **Strain** | : | |
| **Sex** | : | Males and Females |
| **Route of admin.** | : | oral |
| **Exposure period** | : | 42 days |
| **Frequency of treatment** | : | Daily |
| **Duration of test** | : | 42 days |
| **Doses** | : | |
| **Control group** | : | yes |
| **Year** | : | 2007 |
| **GLP** | : | Yes |
| **Test substance** | : | Co stearate |
| **Method** | : | OECD 422 |
| **Method detail** | : | A combined repeated dose toxicity study with a reproduction/developmental toxicity screening test was conducted with Cobalt (II) Stearate. Crl:CD(SD) rats (12/sex/dose level) were dosed with Cobalt (II) Stearate in 0.1% Tween-80 in 0.5% aqueous methylcellulose (5 mL/kg ) once daily, by gavage, at dose levels of 0, 5, 15, or 40 mg/kg/day for males and 0, 5, 15, or 100 mg/kg/day for females. Following a 2-week premating period, $P_1$ males and females were cohoused for up to 2 weeks within their respective treatment groups to produce $F_1$ litters. Dams were allowed to deliver and rear their offspring until postpartum day 4. Careful clinical observations were recorded once daily within 3 hours following dosing. More detailed clinical observations were recorded once during pretest and weekly thereafter. Body weights and food consumption were recorded weekly for $P_1$ males and females (premating), on days 0, 7, 14, and 21 of gestation and on days 0 and 4 of lactation. Food consumption was not measured during cohabitation or thereafter for males, or for females with no evidence of copulation. An abbreviated neurobehavioral evaluation consisting of a functional observational battery and motor activity was conducted in $P_1$ rats (12/sex/group) once during pretest and prior to cohabitation. Clinical pathology parameters were measured in $P_1$ rats (5/sex/group) at the end of the premating period (hematology, clinical chemistry) and at terminal sacrifice (coagulation). $F_1$ litter examinations (pup viability, individual pup weights, clinical observations) were performed at birth and on lactation day 4. |

**Result** : **The following effects were considered to be related to treatment:**

***100 mg/kg/day:***

- Mortality and clinical signs of toxicity, decreased body weight, body weight gain, food consumption and food efficiency in $P_1$ females during gestation
- Decreased body weight and food consumption of $P_1$ females during lactation
- Decreased number of pups born alive

- Microscopic pathology effects in $P_1$ females

***15 mg/kg/day:***

- Clinical signs of toxicity in $P_1$ females during gestation
- Food consumption in $P_1$ females during gestation and lactation
- Number of pups born alive and number of pups on day 4 of lactation.
- Microscopic pathology effects in $P_1$ females.
- **There were no effects on the following parameters**:
- Body weight, food consumption, food efficiency, mortality, and clinical signs in $P_1$ males
- Body weight, food consumption, food efficiency, mortality, and clinical signs in 5, 15, and 100 mg/kg/day $P_1$ females during premating
- Body weight, food consumption, food efficiency, mortality, and clinical signs in 5 mg/kg/day $P_1$ females during gestation, and lactation periods
- Functional observational battery, motor activity or grip strength in $P_1$ males and females
- Hematology, coagulation, and clinical chemistry parameters in $P_1$ males and females
- Mating, fertility, precoital interval, gestation length, *corpora lutea*, number of implantation sites, and implantation efficiency in the $P_1$ generation
- Number of pups born, sex ratio, and pup survival indices during the lactation period in $F_1$ litters from 5 and 15 mg/kg/day groups
- Litter clinical observations and mean pup weights on days 0-4 of lactation in $F_1$ litters
- Gross pathology and organ weights in $P_1$ males and females
- Microscopic pathology in $P_1$ males

Under the conditions of this study, the no-observed-effect level (NOEL)[1] for systemic and reproductive toxicity for $P_1$ females was considered 5.0 mg/kg/day based on decreased body weight and food consumption, clinical signs of toxicity, mortality, microscopic pathology effects, and a decreased number of pups born alive at 15 and/or 100 mg/kg/day. The no-observed-

[1] The NOEL for this study is defined as the highest dose at which toxicologically important effects attributable to the test substance were not detected. Thus, for this study, the NOEL is equivalent to the NOEL as defined by the United States Environmental Protection Agency (1985) and to the no-observed-adverse-effect level (NOAEL) as defined by the European Union (1994).

effect level (NOEL)[2] for P1 males was 40 mg/kg/day, the highest level tested.

**Remark** : **Supporting information for dissociation products:**
**Metal:**Male mice exposed to cobalt chloride hexahydrate in drinking water for 12-13 weeks demonstrated effects on testicular weight and sperm concentration at all dose levels (23 - 58.9 mg Co/kg bw). Rats exposed to 20 mg Co/kg bw (as cobalt chloride hexahydrate) through the diet showed degenerative and necrotic lesions in seminiferous tubules and testicular atrophy (Appendix C).

**Reliability** :
**Reference** :

## 6.0 OTHER INFORMATION

## 6.1 CARCINOGENICITY

**Supporting information for dissociation products:**
**Metal:** The US National Toxicology Program does not recognize cobalt as a human carcinogen, but IARC has classified cobalt and cobalt compounds as possibly carcinogenic to humans (Class 2B) based on sufficient evidence that cobalt metal powder and cobaltous oxide are carcinogenic in animals (Barceloux 1999, ATSDR Sept 2001 Draft). “No studies were located regarding carcinogenic effects in animals after oral exposure to stable [non-radioactive] cobalt.” (ATSDR Sept 2001 Draft).

201-14783

# Final Submission for Tall Oil Fatty Acids and Related Substances

**Pine Chemicals Association**
**August 2004**

## VII. Robust Summaries of Data for Tall Oil Fatty Acids and Related Substances



| PHYSICO-CHEMICAL PROPERTY – WATER SOLUBILITY | |
|---|---|
| ***Test Substance*** | |
| Chemical Name | Tall oil fatty acid |
| CAS # | 61790-12-3 |
| Remarks | This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | Testing was conducted according to OECD Test Method 105, Water Solubility |
| Test Type | Water solubility |
| GLP (Y/N) | Y |
| Year (Study Performed) | 2003 |
| Test conditions | Tall oil fatty acid (TOFA) was tested for water solubility by weighing 0.5 g of the test material into an Erlenmeyer flask and adding 120 to 150 ml of Milli-Q water. Samples were prepared in triplicate. The flasks were then shaken orbitally at 150 r.p.m. at 30 $^{0}$C ± 1 $^{0}$C for 72 h. A Milli-Q water blank was prepared in the same manner, without test material. At the end of the shaking period, the flasks were transferred to a water bath at 20 $^{0}$C ± 1 $^{0}$C for 24 h.<br><br>100 ml of the clear supernatant/filtrate was then adjusted to pH2 with phosphoric acid and extracted using solid phase extraction cartridges, evaporated to residue, reconstituted in an internal standard solution and derivatized with trimethylphenylammonium hydroxide (TMPAH). The test samples were then assayed by gas chromatography (GC) using flame ionization detection (FID). Myristic acid methyl ester was used as the internal standard. |
| ***Results*** | The water solubility of tall oil fatty acid, in its entirety as a complex mixture, is 12.6 mg/l at 20 $^{0}$C. |
| ***Data Quality*** | Reliable without restrictions – Klimisch Code 1a |
| ***References*** | Dinwoodie, N.B. 2003. Determination of the Water Solubility of Tall Oil Fatty Acids and Related Products. Report No. 23304, Inveresk Research, Tranent, Scotland. |

| PHYSICO-CHEMICAL PROPERTY – WATER SOLUBILITY | |
|---|---|
| ***Test Substance*** | |
| Chemical Name | Fatty acids, tall oil, low boiling |
| CAS # | 65997-03-7 |
| Remarks | This substance is also referred to as tall oil heads in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | Testing was conducted according to OECD Test Method 105, Water Solubility |
| Test Type | Water solubility |
| GLP (Y/N) | Y |

| | |
|---|---|
| Year (Study Performed) | 2003 |
| Test conditions | Fatty acids, tall oil, low boiling was tested for water solubility by weighing 0.5 g of the test material into an Erlenmeyer flask and adding 120 to 150 ml of Milli-Q water. Samples were prepared in triplicate. The flasks were then shaken orbitally at 150 r.p.m. at 30 $^0$C ± 1 $^0$C for 72 h. A Milli-Q water blank was prepared in the same manner, without test material. At the end of the shaking period, the flasks were transferred to a water bath at 20 $^0$C ± 1 $^0$C for 24 h.<br><br>100 ml of the clear supernatant/filtrate was then adjusted to pH2 with phosphoric acid and extracted using solid phase extraction cartridges, evaporated to residue, reconstituted in an internal standard solution and derivatized with trimethylphenylammonium hydroxide (TMPAH). The test samples were then assayed by gas chromatography (GC) using flame ionization detection (FID). Myristic acid methyl ester was used as the internal standard. |
| ***Results*** | The water solubility of fatty acids, tall oil, low boiling, in its entirety as a complex mixture, is 22.8 mg/l at 20 $^0$C. |
| ***Data Quality*** | Reliable without restrictions – Klimisch Code 1a |
| ***References*** | Dinwoodie, N.B. 2003. Determination of the Water Solubility of Tall Oil Fatty Acids and Related Products. Report No. 23304, Inveresk Research, Tranent, Scotland. |

| **PHYSICO-CHEMICAL PROPERTY – WATER SOLUBILITY** | |
|---|---|
| ***Test Substance*** | |
| Chemical Name | Fatty acids, C16-C18 and C18 unsaturated, branched and linear |
| CAS # | 68955-98-6 |
| Remarks | This substance is also referred to as monomer acid in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | Testing was conducted according to OECD Test Method 105, Water Solubility |
| Test Type | Water solubility |
| GLP (Y/N) | Y |
| Year (Study Performed) | 2003 |
| Test conditions | Monomer acid was tested for water solubility by weighing 0.5 g of the test material into an Erlenmeyer flask and adding 120 to 150 ml of Milli-Q water. Samples were prepared in triplicate. The flasks were then shaken orbitally at 150 r.p.m. at 30 $^0$C ± 1 $^0$C for 72 h. A Milli-Q water blank was prepared in the same manner, without test material. At the end of the shaking period, the flasks were transferred to a water bath at 20 $^0$C ± 1 $^0$C for 24 h.<br><br>100 ml of the clear supernatant/filtrate was then adjusted to pH2 with phosphoric acid and extracted using solid phase extraction cartridges, evaporated to residue, reconstituted in an internal standard solution and derivatized with trimethylphenylammonium hydroxide (TMPAH). The test samples were then assayed by gas chromatography (GC) using flame ionization detection (FID). Myristic acid methyl ester was used as the internal standard. |

| | |
|---|---|
| ***Results*** | The water solubility of monomer acid, in its entirety as a complex mixture, is 15.0 mg/l at 20 $^0$C. |
| ***Data Quality*** | Reliable without restrictions – Klimisch Code 1a |
| ***References*** | Dinwoodie, N.B. 2003. Determination of the Water Solubility of Tall Oil Fatty Acids and Related Products. Report No. 23304, Inveresk Research, Tranent, Scotland. |

| **PHYSICO-CHEMICAL PROPERTY – WATER SOLUBILITY** | |
|---|---|
| ***Test Substance*** | |
| Chemical Name | Octadecanoic acid, branched and linear |
| CAS # | 68201-37-6 |
| Remarks | This substance is also referred to as hydrogenated monomer acid in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | Testing was conducted according to OECD Test Method 105, Water Solubility |
| Test Type | Water solubility |
| GLP (Y/N) | Y |
| Year (Study Performed) | 2003 |
| Test conditions | Octadecanoic acid, branched and linear was tested for water solubility by weighing 0.5 g of the test material into an Erlenmeyer flask and adding 120 to 150 ml of Milli-Q water. Samples were prepared in triplicate. The flasks were then shaken orbitally at 150 r.p.m. at 30 $^0$C ± 1 $^0$C for 72 h. A Milli-Q water blank was prepared in the same manner, without test material. At the end of the shaking period, the flasks were transferred to a water bath at 20 $^0$C ± 1 $^0$C for 24 h.<br><br>100 ml of the clear supernatant/filtrate was then adjusted to pH2 with phosphoric acid and extracted using solid phase extraction cartridges, evaporated to residue, reconstituted in an internal standard solution and derivatized with trimethylphenylammonium hydroxide (TMPAH). The test samples were then assayed by gas chromatography (GC) using flame ionization detection (FID). Myristic acid methyl ester was used as the internal standard. |
| ***Results*** | The water solubility of octadecanoic acid, branched and linear, in its entirety as a complex mixture, is 2.5 mg/l at 20 $^0$C. |
| ***Data Quality*** | Reliable without restrictions – Klimisch Code 1a |
| ***References*** | Dinwoodie, N.B. 2003. Determination of the Water Solubility of Tall Oil Fatty Acids and Related Products. Report No. 23304, Inveresk Research, Tranent, Scotland. |

| **PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT** | |
|---|---|
| ***Test Substance*** | |
| Chemical Name | Tall oil fatty acid |
| CAS # | 61790-12-3 |
| Remarks | This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | Testing was conducted according to OECD Test Method 117, *"Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method"* |

| | |
|---|---|
| Test Type | Partition coefficient |
| GLP (Y/N) | Y |
| Year (Study Performed) | 2002 |
| Test conditions | Tall oil fatty acid and reference materials were dissolved in methanol and the solutions were analyzed in duplicate by HPLC with Refractive Index (RI) and Photodiode Array (PDA) detection using a mobile phase of 25:75 (v/v) Milli-Q water/methanol at pH 2. A mixture of seven materials with known log $P_{ow}$ values was used for reference. |
| ***Results*** | At pH 2, tall oil fatty acid had a partition coefficient range of 4.9 to 7.6. |
| ***Data Quality*** | Reliable without restrictions – Klimisch Code 1a |
| ***Reference*** | Lightbody, S.M., Fisher, K. and Dinwoodie, N.B. 2002. Determination of the Partition Coefficient of Fatty Acids and Fatty Acid Salts. Report No. 20976. Inveresk Research, Tranent, Scotland. |

| **PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT** | |
|---|---|
| ***Test Substance*** | |
| Chemical Name | Tall oil fatty acid |
| CAS # | 61790-12-3 |
| Remarks | This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | Testing was conducted according to OECD Test Method 117, *"Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method"* |
| Test Type | Partition coefficient |
| GLP (Y/N) | Y |
| Year (Study Performed) | 1993 |
| Test conditions | Tall oil fatty acid was dissolved in methanol and the solution was analyzed by HPLC with UV detection using a mobile phase of methanol:buffer (3:1) at pH 2 and pH 7.5. A mixture of seven materials with known log $P_{ow}$ values was used for reference. |
| ***Results*** | At pH 2, the log $P_{ow}$ values of seven components in tall oil fatty acid were 4.4, 7.0, 7.3, 7.5, 7.7, 8.0, and 8.3. At pH 7.5, the log $K_{ow}$ values of six components in tall oil fatty acid were 3.6, 3.8, 4.2, 4.5, 4.7, and 7.4. |
| ***Data Quality*** | Reliable without restrictions – Klimisch Code 1a |
| ***Reference*** | Dybdahl, H.P. 1993. Determination of log $P_{ow}$ for single components in tall oil fatty acid. GLP Study No. 408335/472. Water Quality Institute, Horsh□lm, Denmark. |

| **PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT** | |
|---|---|
| ***Test Substance*** | |
| Chemical Name | Tall oil fatty acids, low boiling |
| CAS # | 65977-03-7 |
| Remarks | This substance is also referred to as tall oil heads in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | Testing was conducted according to OECD Test Method 117, *"Partition Coefficient (n-Octanol/Water) High Performance Liquid* |

| | |
|---|---|
| | *Chromatograph (HPLC) Method"* |
| Test Type | Partition coefficient |
| GLP (Y/N) | Y |
| Year (Study Performed) | 1993 |
| Test conditions | Tall oil heads was dissolved in methanol and the solution was analyzed by HPLC with UV detection using a mobile phase of methanol:buffer (3:1) at pH 2 and pH 7.5. A mixture of seven materials with known log $P_{ow}$ values was used for reference. |
| ***Results*** | At pH 2, the log $P_{ow}$ values of nine components in tall oil heads were 4.4, 6.7, 6.9, 7.0, 7.2, 7.2, 7.4, 7.7, and 7.8. At pH 7.5, the log $P_{ow}$ values of seven components in tall oil heads were 4.6, 6.5, 6.9, 6.9, 7.3, 7.4, and 8.0. |
| ***Data Quality*** | Reliable without restrictions – Klimisch Code 1a |
| ***Reference*** | Dybdahl, H.P. 1993. Determination of log Pow for single components in tall oil heads. GLP Study No. 408335/474. Water Quality Institute, Horsh□lm, Denmark. |

| **PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT** | |
|---|---|
| ***Test Substance*** | |
| Chemical Name | Fatty acids, C16-C18 and C18 unsaturated, branched and linear |
| CAS # | 68955-98-6 |
| Remarks | This substance is also referred to as monomer acid in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | Testing was conducted according to Method A8 of Commission Directive 92/69/EEC |
| Test Type | Partition coefficient |
| GLP (Y/N) | N |
| Year (Study Performed) | 1994 |
| Test conditions | Not specified |
| ***Results*** | Fatty acids, C16 - C18 and C18 unsaturated, branched and linear had a partition coefficient of $7.93 \times 10^4$ at 25°C, or a $Log_{10}$ $P_{ow}$ of 4.90. |
| ***Data Quality*** | Reliable with restrictions – Klimisch Code 2a |
| ***Reference*** | Mullee, D.M. 1994. Determination of partition coefficient. Project ID No. 508/027. SafePharm Laboratories Ltd., Derby, England. |

| **PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT** | |
|---|---|
| ***Test Substance*** | |
| Chemical Name | Octadecanoic acid, branched and linear |
| CAS # | 68201-37-6 |
| Remarks | This substance is also referred to as hydrogenated monomer acid in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | Testing was conducted according to OECD Test Method 117, *"Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method"* |
| Test Type | Partition coefficient |
| GLP (Y/N) | Y |
| Year (Study Performed) | 2002 |
| Test conditions | Octadecanoic acid, branched and linear and reference materials |

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| | were dissolved in methanol and the solutions were analyzed in duplicate by HPLC with Refractive Index (RI) and Photodiode Array (PDA) detection using a mobile phase of 25:75 (v/v) Milli-Q water/methanol at pH 2. A mixture of seven materials with known log $P_{ow}$ values was used for reference. |
| ***Results*** | At pH 2, octadecanoic acid, branched and linear had a partition coefficient range of 5.6 to 6.1. |
| ***Data Quality*** | Reliable without restrictions – Klimisch Code 1a |
| ***Reference*** | Lightbody, S.M., Fisher, K. and Dinwoodie, N.B. 2002. Determination of the Partition Coefficient of Fatty Acids and Fatty Acid Salts. Report No. 20976. Inveresk Research, Tranent, Scotland. |

| **PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT** | |
|---|---|
| ***Test Substance*** | |
| Chemical Name | Fatty acids, tall oil, potassium salts |
| CAS # | 61790-44-1 |
| ***Method*** | |
| Method/Guideline followed | Testing was conducted according to OECD Test Method 117, *"Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method"* |
| Test Type | Partition coefficient |
| GLP (Y/N) | Y |
| Year (Study Performed) | 2002 |
| Test conditions | Fatty acids, tall oil, potassium salts and reference materials were dissolved in methanol and the solutions were analyzed in duplicate by HPLC with Refractive Index (RI) and Photodiode Array (PDA) detection using a mobile phase of 25:75 (v/v) Milli-Q water/methanol at pH 2. A mixture of seven materials with known log $P_{ow}$ values was used for reference. |
| ***Results*** | At pH 2, fatty acids, tall oil, potassium salts had a partition coefficient range of 4.9 to 7.6. |
| ***Data Quality*** | Reliable without restrictions – Klimisch Code 1a |
| ***Reference*** | Lightbody, S.M., Fisher, K. and Dinwoodie, N.B. 2002. Determination of the Partition Coefficient of Fatty Acids and Fatty Acid Salts. Report No. 20976. Inveresk Research, Tranent, Scotland. |

| **PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT** | |
|---|---|
| ***Test Substance*** | |
| Chemical Name | Fatty acids, tall oil, sodium salts |
| CAS # | 61790-45-2 |
| ***Method*** | |
| Method/Guideline followed | Testing was conducted according to OECD Test Method 117, *"Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method"* |
| Test Type | Partition coefficient |
| GLP (Y/N) | Y |
| Year (Study Performed) | 2002 |
| Test conditions | Fatty acids, tall oil, sodium salts and reference materials were dissolved in methanol and the solutions were analyzed in duplicate by HPLC with Refractive Index (RI) and Photodiode Array (PDA) detection using a mobile phase of 25:75 (v/v) Milli-Q water/methanol at pH 2. A mixture of seven materials with known log $P_{ow}$ values was used for reference. |

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| ***Results*** | At pH 2, fatty acids, tall oil, sodium salts had a partition coefficient range of 4.9 to 7.6. |
| ***Data Quality*** | Reliable without restrictions – Klimisch Code 1a |
| ***Reference*** | Lightbody, S.M., Fisher, K. and Dinwoodie, N.B. 2002. Determination of the Partition Coefficient of Fatty Acids and Fatty Acid Salts. Report No. 20976. Inveresk Research, Tranent, Scotland. |

| **ENVIRONMENTAL FATE – BIODEGRADATION** | |
|---|---|
| ***Test Substance*** | |
| Chemical Name | Tall oil fatty acid |
| CAS # | 61790-12-3 |
| Remarks | This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | Testing was conducted according to OECD Test Method 301 D, *"Ready Biodegradability: Closed Bottle Test"* |
| Test Type (aerobic/anaerobic) | Aerobic |
| GLP (Y/N) | Y |
| Year (Study Performed) | 1993 |
| Contact time | 28 days |
| Inoculum | Secondary effluent from Rungsted Treatment plant |
| Test conditions | Inoculum: Secondary effluent was collected from Rungsted Treatment plant.<br><br>Concentration of test chemical: A stock solution of the test material (2 g/L) was prepared in demineralized water by ultra sonication for 5 minutes.<br><br>Test Setup: Test medium was prepared by adding 1 mL each of four solutions (potassium phosphate, magnesium sulfate, calcium chloride, ferric chloride) to 1 liter of demineralized water, which was aerated to an initial oxygen concentration of 9 mg $O_2$/L and inoculated with 1 drop of secondary effluent per liter. The test article was added at 2 mg/L to a part of the inoculated test medium, equivalent to a chemical oxygen demand of 5.03 mg $O_2$/L. Sodium benzoate, the reference compound, was added at 2 mg/L to another part of the inoculated medium (to assess the activity of the inoculum), equivalent to a theoretical oxygen demand of 3.34 mg $O_2$/L. Both the test and reference articles (2 mg/L) were added to a third part of the inoculated medium (to assess possible inhibitory effects of the test article), at a theoretical oxygen demand of 8.37 mg $O_2$/L. Blank controls were prepared using the inoculated medium without test or reference materials. After the samples were prepared, the medium was transferred to calibrated respirometric bottles (BOD bottles), and placed in the dark at 20$^{o}$C. The study was performed in triplicate.<br><br>Sampling frequency: Samples were collected for BOD analysis on days 0, 7, 14, 21, and 28.<br><br>Controls: Yes. |

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| | Method of calculating oxygen demand: Oxygen demand was calculated as the difference between the measured oxygen concentrations at time t and the start of the test. Biological oxygen demand was calculated by subtracting the oxygen demand for the blank controls from the oxygen demand in the bottles containing test and reference compounds. |
| ***Results*** Degradation % after time | 50% after 7 days and 56% after 28 days (test article); 63% after 7 days and 77% after 28 days (sodium benzoate) |
| ***Conclusions*** | The biological oxygen demand for tall oil fatty acid was 50 and 56% of the theoretical oxygen demand after 7 and 28 days, respectively. The rapid oxygen consumption in the first week and the total oxygen demand at the termination of the experiment indicate that the test material was dominated by readily biodegradable compounds. Tall oil fatty acid did not inhibit the respiratory activity of the inoculum. |
| ***Data Quality*** | Reliable without restrictions– Klimisch Code 1a |
| ***Reference*** | Madsen, T. 1993. Biodegradation of tall oil fatty acid. GLP Study No. 308067/472. Water Quality Institute, Horsh□lm, Denmark. |

| **ENVIRONMENTAL FATE – BIODEGRADATION** | |
|---|---|
| ***Test Substance*** | |
| Chemical Name | Tall oil fatty acid |
| CAS # | 61790-12-3 |
| Remarks | This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | Testing was conducted according to OECD Test Method 301 F, *"Manometric respiratory test for biological degradation"* |
| Test Type (aerobic/anaerobic) | Aerobic |
| GLP (Y/N) | Y |
| Year (Study Performed) | 1999 |
| Contact time | 28 days |
| Inoculum | Activated sludge from a municipal sewage treatment plant |
| Test conditions | Inoculum: Activated sludge from the municipal sewage treatment plant in Reutlingen was washed twice with tap water and centrifuged.<br><br>Concentration of test chemical: A stock solution of the test material (101.5 mg/L) was prepared.<br><br>Test Setup: Mineral medium was prepared by adding 10 mL of a potassium phosphate solution and 1 mL each of three other solutions (magnesium sulfate, calcium chloride, ferric chloride) to make a total volume of 1 liter in demineralized water. Six flasks were prepared: two of the test article in mineral medium with inoculum (24 mg/L); two of the mineral medium plus the inoculum (24 mg/L); one of the reference substance [sodium benzoate (98.5 mg/L)] with inoculum (24 mg/L); and one of the test article |

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| | in water with sterilized medium.<br><br>Sampling frequency: Samples were collected for analysis on days 14 and 28.<br><br>Controls: Yes.<br><br>Method of calculating oxygen demand: Biological oxygen demand was calculated by subtracting the oxygen demand for the blank controls from the oxygen demand in the flasks containing test and reference compounds. |
| ***Results*** | |
| Degradation % after time | 84% after 28 days (test article); 97% after 28 days (sodium benzoate) |
| ***Conclusions*** | Eighty-four percent of tall oil fatty acid was biodegraded after 28 days indicating that the organic portion of the test material was readily biodegradable. |
| ***Data Quality*** | Reliable without restrictions– Klimisch Code 1a |
| ***Reference*** | Aniol, S. 1999. Biological degradation (Manometric respirometry test). STZ Project No. 03/99. Steinbeis-Transferzentrum Angewandte und Umwelt-Chemie, Reutungen. |

| **ENVIRONMENTAL FATE – BIODEGRADATION** | |
|---|---|
| ***Test Substance*** | |
| Chemical Name | Tall oil fatty acid |
| CAS # | 61790-12-3 |
| Remarks | This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | Testing was conducted according to the $CO_2$ Evolution Test (Modified Sturm Test), EPA guideline number OPPTS 853.110, *"Ready Biodegradability"* |
| Test Type (aerobic/anaerobic) | Aerobic |
| GLP (Y/N) | N |
| Year (Study Performed) | 1994 |
| Contact time | 29 days |
| Inoculum | Activated sludge from the Servern Trent water sewage treatment plant |
| Test conditions | Inoculum: Activated sludge microorganisms were obtained from the Servern Trent water sewage treatment plant at Belper, Derbyshire. A 1% inoculum was prepared.<br><br>Concentration of test chemical: The test material was used at a concentration of 20 mg/L.<br><br>Test Setup: Culture medium was prepared by adding 10 mL of a potassium phosphate solution and 1 mL each of three other solutions (magnesium sulfate, calcium chloride, ferric chloride) to a final volume of 1 liter in purified water. Twenty-four hours prior to study initiation, vessels were filled with 2400 mL of culture medium and 30 mL of inoculum and aerated over night. On day |

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| | 0 of the study, the test and reference material (sodium benzoate, 10 mg/L) were added and the total volume was increased to 3 liters. The following series of vessels was prepared: culture medium with inoculum; culture medium with inoculum and sodium benzoate; and culture medium with inoculum and test material. The $CO_2$ absorption bottles were connected to the outlet and were sealed. $CO_2$-free air was bubbled through the solution and they were stirred continuously. All experiments were performed in the dark at 20 to 22$^{o}$C.<br><br>Sampling frequency: Samples (2 mL) were collected from the first $CO_2$ absorber vessel on days 0, 1, 2, 3, 6, 8, 10, 14, 16, 18, 20, 22, 24, 27, 28, and 29, and from the second absorber on days 0 and 29.<br><br>Controls: Yes.<br><br>Analysis: Samples from the $CO_2$ absorbers were injected into the inorganic carbon channel of the total carbon analyzer for direct analysis of evolved $CO_2$. The analyses were conducted in triplicate. |
| Degradation % after time | 74% after 28 days (test article); 80% after 28 days (sodium benzoate) |
| ***Conclusions*** | The test article was degraded 74% after 28 days and sodium benzoate was degraded 80% after 28 days. Under the conditions of the OECD guidelines, the test article cannot be considered to be readily biodegradable. |
| ***Data Quality*** | Reliable without restrictions– Klimisch Code 1b |
| ***Reference*** | Sewell, I.G. 1994. Assessment of ready biodegradability using the $CO_2$ evolution test (modified Sturm test). Project No. 508/28. SafePharm Laboratories Ltd., Derby, England. |

| **ENVIRONMENTAL FATE – BIODEGRADATION** | |
|---|---|
| ***Test Substance*** | |
| Chemical Name | Tall oil fatty acids, low boiling |
| CAS # | 65997-03-2 |
| Remarks | This substance is also referred to as tall oil heads in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | Testing was conducted according to OECD Test Method 301 D, *"Ready Biodegradability: Closed Bottle Test"* |
| Test Type (aerobic/anaerobic) | Aerobic |
| GLP (Y/N) | Y |
| Year (Study Performed) | 1993 |
| Contact time | 28 days |
| Inoculum | Secondary effluent from Rungsted Treatment plant |
| Test conditions | Inoculum: Secondary effluent was collected from Rungsted Treatment plant.<br><br>Concentration of test chemical: A stock solution of the test material (2 g/L) was prepared in demineralized water by ultra sonication for 5 minutes. |

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| | Test Setup: Test medium was prepared by adding 1 mL each of four solutions (potassium phosphate, magnesium sulfate, calcium chloride, ferric chloride) to 1 liter of demineralized water, which was aerated to an initial oxygen concentration of 9 mg $O_2$/L and inoculated with 1 drop of secondary effluent per liter. The test article was added at 2.4 mg/L to a part of the inoculated test medium, equivalent to a chemical oxygen demand of 4.94 mg $O_2$/L. Sodium benzoate, the reference compound, was added at 2 mg/L to another part of the inoculated medium (to assess the activity of the inoculum), equivalent to a theoretical oxygen demand of 3.34 mg $O_2$/L. Both the test and reference articles were added to a third part of the inoculated medium (to assess possible inhibitory effects of the test article), at a theoretical oxygen demand of 8.28 mg $O_2$/L. Blank controls were prepared using the inoculated medium without test or reference materials. After the samples were prepared, the medium was transferred to calibrated respirometric bottles (BOD bottles), and placed in the dark at 20°C. The study was performed in triplicate.<br><br>Sampling frequency: Samples were collected for BOD analysis on days 0, 7, 14, 21, and 28.<br><br>Controls: Yes.<br><br>Method of calculating oxygen demand: Oxygen demand was calculated as the difference between the measured oxygen concentrations at time t and the start of the test. Biological oxygen demand was calculated by subtracting the oxygen demand for the blank controls from the oxygen demand in the bottles containing test and reference compounds. |
| ***Results***<br>Degradation % over time | 33% after 7 days and 41% after 28 days (test article); 63% after 7 days and 77% after 28 days (sodium benzoate) |
| ***Conclusions*** | The biological oxygen demand for tall oil heads was 33 and 41% of the theoretical oxygen demand after 7 and 28 days, respectively. These results indicate that the test material contains readily biodegradable and recalcitrant compounds. Tall oil heads did not inhibit the respiratory activity of the inoculum. |
| ***Data Quality*** | Reliable without restrictions– Klimisch Code 1a |
| ***Reference*** | Madsen, T. 1993. Biodegradation of tall oil heads. GLP Study No. 308067/474. Water Quality Institute, Horsh□lm, Denmark. |

| **ENVIRONMENTAL FATE – BIODEGRADATION** | |
|---|---|
| ***Test Substance*** | |
| Chemical Name | Fatty acids, C16 - C18 and C18 unsaturated, branched and linear |
| CAS # | 68955-98-6 |
| Remarks | This substance is also referred to as monomer acid in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |

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| Method/Guideline followed | Testing was conducted according to the $CO_2$ Evolution Test (Modified Sturm Test), EPA guideline number OPPTS 853.110, "*Ready Biodegradability"* |
| Test Type (aerobic/anaerobic) | Aerobic |
| GLP (Y/N) | N |
| Year (Study Performed) | 1994 |
| Contact time | 29 days |
| Inoculum | Activated sludge from the Severn Trent water sewage treatment plant |
| Test conditions | Inoculum: Activated sludge microorganisms were obtained from the Severn Trent water sewage treatment plant at Belper, Derbyshire. A 1% inoculum was prepared.<br><br>Concentration of test chemical: The test material was used at a concentration of 20 mg/L.<br><br>Test Setup: Culture medium was prepared by adding 10 mL of a potassium phosphate solution and 1 mL each of three other solutions (magnesium sulfate, calcium chloride, ferric chloride) to a final volume of 1 liter in purified water. Twenty-four hours prior to study initiation, vessels were filled with 2400 mL of culture medium and 30 mL of inoculum and aerated over night. On day 0 of the study, the test and reference material (sodium benzoate, 10 mg/L) were added and the total volume was increased to 3 liters. The following series of vessels was prepared: culture medium with inoculum; culture medium with inoculum and sodium benzoate; and culture medium with inoculum and test material. The $CO_2$ absorption bottles were connected to the outlet and were sealed. $CO_2$-free air was bubbled through the solution and they were stirred continuously. All experiments were performed in the dark at 21 to 22$^{o}$C.<br><br>Sampling frequency: Samples (2 mL) were collected from the first $CO_2$ absorber vessel on days 0, 1, 2, 3, 6, 8, 10, 12, 14, 16, 20, 22, 24, 27, 28, and 29, and from the second absorber on days 0 and 29.<br><br>Controls: Yes.<br><br>Analysis: Samples from the $CO_2$ absorbers were injected into the inorganic carbon channel of the total carbon analyzer for direct analysis of evolved $CO_2$. The analyses were conducted in triplicate. |
| ***Results***<br>Degradation % after time | 67% after 28 days (test article); 87% after 28 days (sodium benzoate) |
| ***Conclusions*** | The test article was degraded 67% after 28 days. Under the conditions of the OECD guidelines, it cannot be considered to be readily biodegradable. |
| ***Data Quality*** | Reliable without restrictions– Klimisch Code 1b |
| ***Reference*** | Sewell, I.G. 1994. Assessment of ready biodegradability using the CO2 evolution test (modified Sturm test). Project No. 508/23. SafePharm Laboratories Ltd., Derby, England. |

| ENVIRONMENTAL FATE – BIODEGRADATION | |
|---|---|
| ***Test Substance*** | |
| Chemical Name | Octadecanoic acid, branched and linear |
| CAS # | 68201-37-6 |
| Remarks | This substance is also referred to as hydrogenated monomer acid in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | Testing was conducted according to OECD (1992) 301B Modified Sturm Test |
| Test Type (aerobic/anaerobic) | Aerobic |
| GLP (Y/N) | Y |
| Year (Study Performed) | 2002 |
| Contact time | 28 days |
| Inoculum | Activated sludge from the Haddington Municipal Sewage Treatment Works |
| Test conditions | Inoculum: Activated sludge microorganisms were obtained from the Haddington Municipal Sewage Treatment Works. The solids content of the sludge was 3.2 g/l.<br><br>Concentration of test chemical: The test material was used at a concentration of 20 mg DOC/L. Based on the percentage carbon content, a target weight of 53.6 mg of test material was weighed for direct addition to each appropriate bioreactor.<br><br>Test Setup: Each test item bioreactor contained 1980 ml of mineral media, 20 ml of microbial inoculum and 54 mg of test item. The reference bioreactor contained 1911 ml of mineral media, 20 ml of microbial inoculum and 69 ml of reference material (sodium benzoate) stock. The control bioreactors each contained 1980 ml of mineral media and 20 ml of microbial inoculum. The toxicity control bioreactor contained 1911 ml of mineral media, 20 ml of microbial inoculum, 53.9 mg of test item and 69 ml reference material stock.<br><br>Each bioreactor was connected to three traps, each trap containing 100 ml of 0.0125 M $Ba(OH)_2$. At trap collection, the trap closes to the bioreactor was taken for titration, the two remaining traps were moved closer to the bioreactor and a fresh trap was placed third in line from the bioreactor. Trap changes were conducted on days 1, 4, 6, 8, 11, 15, 18, 21, 26, and 29.<br><br>Each sampled trap was titrated with a few drops of phenolphthalein indicator against 0.05M HCl. The pH was determined in each bioreactor on days 0, 28 and 29; if necessary, the pH on day 0 was adjusted to 7.2-7.8.<br><br>Calculation of Results: The weight of $CO_2$ evolved was calculated from the titre. The actual titre for each batch of $Ba(OH)_2$ was used as the background titre. The mean titre for the test, reference and control vessels was calculated according to the following equation:<br><br>Weight $CO_2$ produced (mg) = 1.1 x (background titre – ml HCl |

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| | titrated)<br><br>The net $CO_2$ production was then calculated by subtracting the control mean $CO_2$ production from the test and reference material mean $CO_2$ production values. The percentage biodegradation was calculated by comparing actual $CO_2$ evolved in test and reference vessels with the theoretical $CO_2$ evolution.<br><br>For the test item this was calculated using the DOC addition rate:<br>$\% \text{ degradation} = \frac{\text{Mg } CO_2 \text{ produced}}{\text{mg DOC added} \times 3.67^{*}} \times 100$<br><br>* = where 3.67 is the conversion factor (44/12) for carbon to $CO_2$ |
| ***Results***<br>Degradation % after time | 46.72% after 28 days (test article); 68.39% after 28 days (sodium benzoate) |
| ***Conclusions*** | The test article was degraded 47% after 28 days. Under the conditions of the OECD guidelines, it cannot be considered to be readily biodegradable. |
| ***Data Quality*** | Reliable without restrictions– Klimisch Code 1a |
| ***Reference*** | Kelly, C.R. 2002. Octadecanoic acid, branched and linear, CAS No. 68201-37-6 Determination of Ready Biodegradability by the Modified Sturm Test. Report No. 21136. Inveresk Research, Tranet, Scotland. |

| **ENVIRONMENTAL FATE – BIODEGRADATION** | |
|---|---|
| ***Test Substance*** | |
| Chemical Name | Fatty acids, tall oil, sodium salt |
| CAS # | 61790-45-2 |
| ***Method*** | |
| Method/Guideline followed | Testing was conducted according to OECD (1992) 302B Modified Zahn-Wellens Test |
| Test Type (aerobic/anaerobic) | Aerobic |
| GLP (Y/N) | Y |
| Year (Study Performed) | 2002 |
| Contact time | 28 days |
| Inoculum | Activated sludge from the Haddington Municipal Sewage Treatment Works |
| Test conditions | Inoculum: Activated sludge microorganisms were obtained from the Haddington Municipal Sewage Treatment Works. The solids content of the sludge was 4.0 g/l.<br><br>Concentration of test chemical: The test material was used at a concentration of 200 mg DOC/L equivalent to 4480 mg of fatty acid, tall oil, sodium salt per 2.5 liter bioreactor based on percentabe carbon content. To prepare the reference material (aniline) 8.09 ml was added to 1000 ml DI water and sonicated for *ca* 30 min. to aid dissolution; from this stock 125 ml aliquots were added to each appropriate bioreactor. |

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| | Test Setup: The activated sludge was introduced to the test system at a ratio of 2.5:1 sludge solids/l to test item DOC/l which required the addition of 250 ml of 4 g/l sludge to each bioreactor. A total of six bioreactors were used.<br><br>Each bioreactor had a final volume of 2000 ml; the control bioreactors each contained 250 ml sludge and 1750 ml of mineral medium; the reference bioreactor contained 250 ml sludge, 125 ml of aniline stock solution and 1625 of mineral medium; the test item bioreactors each contained 250 ml sludge, the appropriate weight of test item and 1750 ml of mineral medium; the toxicity control bioreactor contained 250 ml sludge, the appropriate weight of test item, 125 ml aniline stock and 1625 ml mineral medium. The test was conducted over 28 days. DOC measurements were conducted on duplicate samples 3 h after test initiation, and on Days 14 and 28.<br><br>Sampling Procedure: Prior to each sampling point the liquid in each vessel was replenished to its starting level. The pH and dissolved oxygen concentration were recorded. If necessary the pH was adjusted to 6.5-8.0 using $H_2SO_4$ as appropriate. A *ca* 25 ml sample was extracted from each vessel using a syringe and allowed to settle after which it was passed through a 0.45um filter for DOC analysis. Determination of DOC, total organic carbon (TOC), total carbon (TC) and inorganic carbon (IC) were determined.<br><br>Calculation of Results: All measurements were conducted on duplicate samples. Dissolved organic carbon (DOC) values were calculated as follows:<br><br>$DOC = TC - IC$<br><br>The percentage degradation (Dt) at each timepoint was calculated using mean DOC measurements from the duplicate samples, using the following equation:<br><br>$Dt = \left(1 - \frac{Ct - Cb}{Ca - Cba}\right) \times 100$<br><br>Where:<br><br>Ct = mean DOC concentration in test/reference at time t<br>Cb = mean DOC concentration in controls at time t<br>Ca = mean DOC concentration in test/reference at 3 h ± 0.5 h<br>Cba = mean DOC concentration in controls at 3 h ± 0.5 h |
| ***Results***<br>Degradation % after time | The test item reached 73.8 % degradation by Day 14 and 98.4 % by Day 28; the material reached 97% degradation by Day 14. |
| ***Conclusions*** | The test article was degraded 98% after 28 days under the conditions of the test. |
| ***Data Quality*** | Reliable without restrictions– Klimisch Code 1a |
| ***Reference*** | Kelly, C.R. 2002. Fatty acid, tall oil, sodium salt, CAS No. 61790-45-2 Determination of Inherent Biodegradability by the |

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| | Modified Zahn-Wellens Test. Report No. 21485. Inveresk Research, Tranet, Scotland. |

| **ENVIRONMENTAL FATE – BIODEGRADATION** | |
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| ***Test Substance*** | |
| Chemical Name | Tall oil fatty acids, potassium salt |
| CAS # | 61790-44-1 |
| ***Method*** | |
| Method/Guideline followed | Testing was conducted according to a modified OECD test for ready biodegradability, EPA guideline number OPPTS 853.110, *"Ready Biodegradability"* |
| Test Type (aerobic/anaerobic) | Aerobic |
| GLP (Y/N) | Y |
| Year (Study Performed) | 1991 |
| Contact time | 28 days |
| Inoculum | Activated sludge from Bergen County sewage treatment plant |
| Test conditions | Inoculum: Activated sludge from Bergen County sewage treatment plant was mixed with soil extract and surface water to prepare the inoculum.<br><br>Concentration of test chemical: The test article was tested at a concentration of 20 to 25 ppm.<br><br>Test Setup: OECD test medium was used. Aniline was the reference material and was tested at a concentration of 20 to 25 ppm. The experiments were performed in the dark at 20 to 25$^{o}$C.<br><br>Sampling frequency: Samples were collected for analysis on days 0, 7, 14, 21, and 28.<br><br>Controls: Yes.<br><br>Method of calculating degradation: The mean initial concentration of soluble organic carbon (SOC) in the controls is subtracted from the initial concentration in the test sample. From this is subtracted, the mean initial concentration of SOC in the test and control samples at time t. This value is divided by the mean initial concentration of SOC in the controls subtracted from the initial concentration in the test sample. |
| ***Results*** | |
| Degradation % after time | 79% after 28 days (test article); 97% after 28 days (aniline) |
| ***Conclusions*** | The test material degraded 79% and is considered to be readily biodegradable as defined by OECD. |
| ***Data Quality*** | Reliable without restrictions– Klimisch Code 1b |
| ***Reference*** | Drozdowki, D. 1991. Modified OECD test for ready biodegradability of [product name deleted] tall oil fatty acid potassium salt. Report No. 063383-1. United States Testing Company, Inc., Hoboken, New Jersey. |

| ECOTOXICITY – ACUTE TOXICITY TO FISH | |
|---|---|
| ***Test substance*** | |
| Chemical Name | Tall oil fatty acid |
| CAS # | 61790-12-3 |
| Remarks | This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | OECD Test Method 203, *"Testing of Chemicals, Fish Acute Toxicity Test"* and following procedures in OECD (2000) Guidance Document No. 23 on Testing Difficult Substances. |
| Year | 2002 |
| GLP (Y/N) | Y |
| System of testing | Fathead minnows (*Pimephales promelas)* under static conditions. |
| Concentration | 0, 1, 10, 100 and 1000 mg/l |
| ***Results*** | The 96 hr $LL_{50}$ was > 1000 mg/l the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) was 1000 mg/l. |
| ***Detailed Summary*** | Tall oil fatty acid (TOFA) was tested in fathead minnows under static conditions to determine the acute toxicity. Water accommodated fractions (WAF) were prepared using the same conditions as those used to determine the water solubility of this substance. Appropriate weights of TOFA were added to a stirring medium in glass vessels which were sealed to avoid loss of volatile fractions. Using magnetic stirrers, the stirring speed was adjusted to give a stirring vortex 5-10% of the water column. After a stirring period of approximately 48 hr. the test solutions were allowed to settle for ca hour. The WAF was then removed via a glass siphon taking care not to remove undissolved material at the top of bottom of the water column. The test organisms were exposed to this WAF. This procedure was adopted to maximize the solubility of the test item under specific test exposure conditions, but to reduce exposure to the test organisms to insoluble fractions. A control medium without the addition of the test item was stirred and extracted in an identical ways as the treated media. The effects of both filtering and adjusting pH were investigated in a range finding test using the highest loading rate (i.e., 1000 mg/l). Because no mortality or other effects were observed in the range finding tests, a definitive-limit test was conducted at the maximum loading rate of 1000 mg/l. The 96 hr $LL_{50}$ was > 1000 mg/l, the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) was 1000 mg/l. |
| ***Data Quality*** | Valid without restriction – Klimisch Code 1a |
| ***Reference*** | Kelly, C. 2002. Fatty acids, tall oil, CAS No. 61790-12-3 Determination of Acute Toxicity ($LL_{50}$ ) to Fathead Minnows (96 h, Static). Report No. 20621. Inveresk Research, Tranent, Scotland. |

| ECOTOXICITY – ACUTE TOXICITY TO FISH | |
|---|---|
| ***Test substance*** | |
| Chemical Name | Fatty acids, C16-C18 and C18 unsaturated, branched and linear |
| CAS # | 68955-98-6 |
| Remarks | This substance is also referred to as monomer acid in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |

| ***Method*** | |
|---|---|
| Method/Guideline followed | OECD Test Method 203, *"Testing of Chemicals, Fish Acute Toxicity Test."* |
| Year | 1994 |
| GLP (Y/N) | Y |
| System of testing | Golden orfe (*Leuciscus idus.)* under static conditions. |
| Concentration | 1000 mg/l |
| ***Results*** | The 96 hr $LL_{50}$ was > 1000 mg/l the highest loading rate tested. The No Observed Effect Concentration Loading Rate ($NOEC_r$) was 1000 mg/l. |
| ***Detailed Summary*** | Fatty acid, C16 and C18 and C18 unsaturated, branched and linear was tested in golden orfe under static conditions to determine the acute toxicity. A range finding test was conducted during which no mortality was observed at a concentration of 1000 mg/l. For the definitive test, water accommodated fractions (WAF) were prepared by placing 1000 mg/l of test material on the surface of dechlorinated tap water. This was stirred using a magnetic stirrer for 24 hr prior to the test with care taken to avoid the formation of a vortex during mixing. After 24 hr. the mixture was allowed to stand for 1 hr. prior to removing the aqueous phase (i.e., WAF) by a siphon to glass exposure vessels for testing. The test organisms were exposed to this WAF. Because no mortality or other effects were observed in the range finding tests, a definitive-limit test was conducted at the maximum loading rate of 1000 mg/l. There were no mortalities or other adverse reactions in 20 fish exposed to a 1000 mg/l WAF loading rate for a period of 96 hr. The 96 hr $LL_{50}$ was > 1000 mg/l, the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) was 1000 mg/l. |
| ***Data Quality*** | Valid without restriction – Klimisch Code 1a |
| ***Reference*** | Sewell, I.G. 1994. [Fatty acid, C16 and C18 and C18 unsaturated, branched and linear] Acute Toxicity to Golden Orfe. SafePharm Laboratories Ltd. Durham, England. |

| **ECOTOXICITY – ACUTE TOXICITY TO FISH** | |
|---|---|
| ***Test substance*** | |
| Chemical Name | Fatty acids, C16-C18 and C18 unsaturated, branched and linear, calcium salt |
| CAS # | Not assigned |
| Remarks | This substance is also referred to as monomer acid calcium salt in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | OECD Test Method 203, *"Testing of Chemicals, Fish Acute Toxicity Test."* |
| Year | 2002 |
| GLP (Y/N) | Y |
| System of testing | Rainbow trout (*Oncorhynchus mykiss.)* under static conditions. |
| Concentration | 100 mg/l |
| ***Results*** | The 96 hr $LL_{50}$ was > 100 mg/l the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) was 100 mg/l. |
| ***Detailed Summary*** | Monomer acid, calcium salt was tested in rainbow trout under |

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|---|---|
| | static conditions to determine the acute toxicity. A range finding test was conducted during which no mortality was observed at a concentration of 100 mg/l. It was considered unnecessary and unrealistic to test at loading rates in excess of 100 mg/l. For the definitive test, water accommodated fractions (WAF) were prepared by placing 2100 mg of test material on the surface of 21L of dechlorinated tap water to yield the 100 mg/l loading rate. This was stirred using a magnetic stirrer for 23 hr prior to the test with care taken to ensure that the vortex formed was only a dimple on the water surface. After 23 hr. the mixture was allowed to stand for 1 hr. prior to removing the aqueous phase (i.e., WAF) by a siphon to glass exposure vessels for testing. Microscopic inspection of the WAF showed no micro-dispersions or undissolved test material. The test organisms were exposed to this WAF. Because no mortality or other effects were observed in the range finding tests, a definitive-limit test was conducted at the maximum loading rate of 100 mg/l. There were no mortalities or other adverse reactions in 20 fish exposed to a 100 mg/l WAF loading rate for a period of 96 hr. The 96 hr $LL_{50}$ was > 100 mg/l, the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) was 100 mg/l. |
| ***Data Quality*** | Valid without restriction – Klimisch Code 1a |
| ***Reference*** | Shacklady, L.G. and Mullee, D.M. 2002. [Monomer acid, calcium salt] Acute Toxicity to Rainbow Trout (*Oncorhynchus* mykiss). SPL Proj. No. 1078/087. SafePharm Laboratories Ltd. Durham, U.K. |

| **ECOTOXICITY – ACUTE TOXICITY TO DAPHNIA** | |
|---|---|
| ***Test substance*** | |
| Chemical Name | Tall oil fatty acid |
| CAS # | 61790-12-3 |
| Remarks | This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | OECD Test Method 202, Part 1 *"Testing of Chemicals, Daphnia sp. Acute Immobilization Test"* and following procedures in OECD (2000) Guidance Document No. 23 on Testing Difficult Substances. |
| Year | 2002 |
| GLP (Y/N) | Y |
| System of testing | *Daphnia magna* (water fleas) under static conditions. |
| Concentration | 0, 1, 10, 100 and 1000 mg/l |
| ***Results*** | The 48 hr $EL_{50}$ was > 1000 mg/l the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) was 1000 mg/l. |
| ***Detailed Summary*** | Tall oil fatty acid (TOFA) was tested in daphnia under static conditions to determine the acute toxicity. Water accommodated fractions (WAF) were prepared using the same conditions as those used to determine the water solubility of this substance. Appropriate weights of TOFA were added to a stirring medium in glass vessels which were sealed to avoid loss of volatile fractions. Using magnetic stirrers, the stirring speed was adjusted to give a stirring vortex 5-10% of the water column. After a stirring period of approximately 48 hr. the test solutions |

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|---|---|
| | were allowed to settle for ca hour. The WAF was then removed via a glass siphon taking care not to remove undissolved material at the top of bottom of the water column. The test organisms were exposed to this WAF. This procedure was adopted to maximize the solubility of the test item under specific test exposure conditions, but to reduce exposure to the test organisms to insoluble fractions. A control medium without the addition of the test item was stirred and extracted in an identical ways as the treated media. The effects of both filtering and adjusting pH were investigated in a range finding test. Because no mortality or other effects were observed in the range finding tests, a definitive-limit test was conducted at the maximum loading rate of 1000 mg/l. The 48 hr $EL_{50}$ was > 1000 mg/l, the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) was 1000 mg/l. |
| ***Data Quality*** | Valid without restriction – Klimisch Code 1a |
| ***Reference*** | Kelly, C. 2002. Fatty acids, tall oil, CAS No. 61790-12-3 Determination of Acute Toxicity ($EL_{50}$) to Daphnia (48 h, Static). Report No. 20468. Inveresk Research, Tranent, Scotland. |

| **ECOTOXICITY – ACUTE TOXICITY TO DAPHNIA** | |
|---|---|
| ***Test substance*** | |
| Chemical Name | Fatty acids, C16-C18 and C18 unsaturated, branched and linear |
| CAS # | 68955-98-6 |
| Remarks | This substance is also referred to as monomer acid in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | OECD Test Method 202, Part 1 *"Testing of Chemicals, Daphnia sp. Acute Immobilization Test"* |
| Year | 1994 |
| GLP (Y/N) | Y |
| System of testing | Daphnia (*Daphnia magna.)* under static conditions. |
| Concentration | 1000 mg/l |
| ***Results*** | The 48 hr Effective Loading Rate ($ELR_{50}$) was > 1000 mg/l the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) at both 24 and 48 hr. was 1000 mg/l. |
| ***Detailed Summary*** | Fatty acid, C16 and C18 was tested in daphnia under static conditions to determine the acute toxicity. A range finding test was conducted during which no mortality was observed at a concentration (i.e., loading rate) of 1000 mg/l. For the definitive test, water accommodated fractions (WAF) were prepared by placing 1000 mg/l of test material on the surface of appropriate daphnia media. This was stirred using a magnetic stirrer for 24 hr prior to the test with care taken to avoid the formation of a vortex during mixing. After 24 hr. the mixture was allowed to stand for 1 hr. prior to removing the aqueous phase (i.e., WAF) by a siphon to glass exposure vessels for testing. The test organisms were exposed to this WAF. Because no mortality or other effects were observed in the range finding tests, a definitive-limit test was conducted at the maximum loading rate of 1000 mg/l. There were no immobilized daphnia or other adverse reactions in 40 daphnids exposed to a 1000 mg/l WAF loading rate for a period of 48 hr. The 48 hr Effective Loading Rate ($ELR_{50}$) was > 1000 |

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| | mg/l the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) at both 24 and 48 hr. was 1000 mg/l. |
| ***Data Quality*** | Valid without restriction – Klimisch Code 1a |
| ***Reference*** | Sewell, I.G. 1994. [Fatty acid, C16 and C18] Acute Toxicity to Daphnia Magna. SafePharm Laboratories Ltd. Durham, England. |

| **ECOTOXICITY – ACUTE TOXICITY TO DAPHNIA** | |
|---|---|
| ***Test substance*** | |
| Chemical Name | Fatty acids, C16-C18 and C18 unsaturated, branched and linear, calcium salt |
| CAS # | Not assigned |
| Remarks | This substance is also referred to as monomer acid calcium salt in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | OECD Test Method 202, Part 1 *"Testing of Chemicals, Daphnia sp. Acute Immobilization Test"* |
| Year | 2002 |
| GLP (Y/N) | Y |
| System of testing | Daphnia (*Daphnia* magna) under static conditions. |
| Concentration | 100 mg/l |
| ***Results*** | The 48 hr $EL_{50}$ was > 100 mg/l the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) was 100 mg/l. |
| ***Detailed Summary*** | Monomer acid, calcium salt was tested in daphnia under static conditions to determine the acute toxicity. A range finding test was conducted during which no mortality was observed at a concentration of 100 mg/l. It was considered unnecessary and unrealistic to test at loading rates in excess of 100 mg/l. For the definitive test, water accommodated fractions (WAF) were prepared by placing 1000 mg of test material on the surface of 10L of daphnia media to yield the 100 mg/l loading rate. This was stirred using a magnetic stirrer for 23 hr prior to the test with care taken to ensure that the vortex formed was only a dimple on the water surface. After 23 hr. the mixture was allowed to stand for 1 hr. prior to removing the aqueous phase (i.e., WAF) by a siphon to glass exposure vessels for testing. Microscopic inspection of the WAF showed no micro-dispersions or undissolved test material. The test organisms were exposed to this WAF. Because no mortality or other effects were observed in the range finding tests, a definitive-limit test was conducted at the maximum loading rate of 100 mg/l. There were no mortalities or other adverse reactions in 40 daphnia exposed to a 100 mg/l WAF loading rate for a period of 48 hr. The 48 hr $EL_{50}$ was > 100 mg/l, the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) was 100 mg/l. |
| ***Data Quality*** | Valid without restriction – Klimisch Code 1a |
| ***Reference*** | Shacklady, L.G. and Mullee, D.M. 2002. [Monomer acid, calcium salt] Acute Toxicity to *Daphnia Magna* SPL Proj. No. 1078/088. SafePharm Laboratories Ltd. Durham, U.K. |

| ECOTOXICITY – ALGA, GROWTH INHIBITION | |
|---|---|
| ***Test substance*** | |
| Chemical Name | Tall oil fatty acid |
| CAS # | 61790-12-3 |
| Remarks | This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | OECD Test Method 201, *"Testing of Chemicals, Alga, Growrh Inhibition Test"* and following procedures in OECD (2000) Guidance Document No. 23 on Testing Difficult Substances. |
| Year | 2002 |
| GLP (Y/N) | Y |
| System of testing | Green alga (*Selenastrum capriconutum)* growth inhibition. |
| Concentration | 0, 125, 250, 500 and 1000 mg/l |
| ***Results*** | The 72 hr $EL_{50}$ for area under growth curve (AUC) was 854.90 mg/l with a corresponding No Observed Effect Loading Rate ($NOEL_r$) of 500 mg/l. The 72 hr. $EL_{50}$ based on Average Specific Growth Rate was > 1000 mg/l with a corresponding $NOEL_r$ of 500 mg/l. at 0-48 hr and 750 mg/l at 0-72 hr. indicating some inhibition (<50%) compared to the control. |
| ***Detailed Summary*** | Tall oil fatty acid (TOFA) was tested in alga to determine the median effective loading ($EL_{50}$) for growth inhibition. Water accommodated fractions (WAF) were prepared using the same conditions as those used to determine the water solubility of this substance. Appropriate weights of TOFA were added to a stirring medium in glass vessels which were sealed to avoid loss of volatile fractions. Using magnetic stirrers, the stirring speed was adjusted to give a stirring vortex 5-10% of the water column. After a stirring period of approximately 48 hr. the test solutions were allowed to settle for ca hour. The WAF was then removed via a glass siphon taking care not to remove undissolved material at the top of bottom of the water column. The test organisms were exposed to this WAF. This procedure was adopted to maximize the solubility of the test item under specific test exposure conditions, but to reduce exposure to the test organisms to insoluble fractions. A control medium without the addition of the test item was stirred and extracted in an identical ways as the treated media. The effects of both filtering and adjusting pH were investigated in a range finding test at the highest loading rate. In the range finding test there was a 29% inhibitioin of growth at 1000 mg/l; after 72 hr. exposure cell numbers in all test solutions < 100 mg/l were higher than the standard controls. Based on the results of the range-finding test a definitive test was conducted at loading rates of 0, 125, 250, 500, 750 and 1000 mg/l. This test was conducted using an unfiltered WAF with no pH adjustment.<br><br>The 72 hr $EL_{50}$ for area under growth curve (AUC) was 854.90 mg/l with a corresponding No Observed Effect Loading Rate ($NOEL_r$) of 500 mg/l. The 72 hr. $EL_{50}$ based on Average Specific Growth Rate was > 1000 mg/l with a corresponding $NOEL_r$ of 500 mg/l. at 0-48 hr and 750 mg/l at 0-72 hr. indicating some inhibition (<50%) compared to the control. |

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| ***Data Quality*** | Valid without restriction – Klimisch Code 1a |
| ***Reference*** | Kelly, C. 2002. Fatty acids, tall oil, CAS No. 61790-12-3 Alga, Growth Inhibition Test (72 h, $EL_{50}$). Report No. 20706. Inveresk Research, Tranent, Scotland. |

| **ECOTOXICITY – ALGA, GROWTH INHIBITION** | |
|---|---|
| ***Test substance*** | |
| Chemical Name | Fatty acids, C16-C18 and C18 unsaturated, branched and linear |
| CAS # | 68955-98-6 |
| Remarks | This substance is also referred to as monomer acid in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | OECD Test Method 201, *"Testing of Chemicals, Alga, Growrh Inhibition Test"* |
| Year | 1994 |
| GLP (Y/N) | Y |
| System of testing | Alga (*Scenedesmus subspicatus)* under static conditions. |
| Concentration | 1000 mg/l |
| ***Results*** | The 72 hr Effective Loading Rate that reduced biomass by 50% ($E_bLR_{50}$) was > 1000 mg/l WAF loading rate and the 24 hr Effective Loading Rate that reduced specific growth rate by 50% ($E_rLR_{50}$) was > 1000 mg/l WAF loading rate. |
| ***Detailed Summary*** | Fatty acid, C16 and C18 was tested in alga under static conditions to determine the extent of growth inhibition. A water accommodated fraction (WAF) was prepared by placing 2000 mg/l of test material on the surface of alga culture medium. This was stirred using a magnetic stirrer for 24 hr prior to the test with care taken to avoid the formation of a vortex during mixing. After 24 hr. the mixture was allowed to stand for 1 hr. prior to removing the aqueous phase (i.e., WAF) for testing. This 2000 mg/l WAF loading rate was diluted 50:50 with algal suspension to give a 1000 mg/l WAF loading rate. The test organisms were exposed to this WAF; six replicates were used. Samples were taken at 0, 24, 48 and 72 hrs. Cell densities of control and test cultures at 0 and 72 hrs. were determined by direct counting with a haemocytometer. Neither the growth nor the biomass of alga were affected by the presence of the test compound over the 72 hr. exposure period. The 72 hr Effective Loading Rate that reduced biomass by 50% ($E_bLR_{50}$) was > 1000 mg/l WAF loading rate and the 24 hr Effective Loading Rate that reduced specific growth rate by 50% ($E_rLR_{50}$) was > 1000 mg/l WAF loading rate. |
| ***Data Quality*** | Valid without restriction – Klimisch Code 1a |
| ***Reference*** | Sewell, I.G. 1994. Assessment of the Algistatic Effect of [Fatty acid, C16 and C18]. SafePharm Laboratories Ltd. Durham, England. |

| **ACUTE TOXICITY – ORAL** | |
|---|---|
| ***Test substance*** | |
| Chemical Name | Tall oil fatty acid |
| CAS # | 61790-12-3 |
| Remarks | This substance is also referred to as TOFA in the Final Data |

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|---|---|
| | Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | Test procedure was consistent with OECD Test Method 401, *"Acute Oral Toxicity"* |
| GLP (Y/N) | Y |
| Year (Study Performed) | 1983 |
| Species | Rat |
| Strain | Sprague-Dawley |
| Route of administration | Oral |
| Dose levels | 10,000 mg/kg |
| Sex and number/group | 5 male and 5 female rats |
| Frequency of treatment | Single oral gavage |
| Duration of test | 14 day observation post-treatment |
| Control group (Y/N) | N |
| ***Result*** | |
| Acute Oral $LD_{50}$ | >10,000 mg/kg |
| ***Detailed Summary*** | Sprague-Dawley rats (n = 5/sex) received a single oral (gavage) dose of 10,000 mg/kg of fatty acid, tall oil (CAS #61790-12-3) and were observed for 14 days. Parameters evaluated included clinical signs, mortality, body weight, and gross pathology. None of the animals died. One hour post-dosing, piloerection was observed in one male and abnormal stance was observed in one male and one female. By four hours, these effects had resolved. No body weight effects were observed. Gross necropsy revealed no treatment-related effects. The acute oral $LD_{50}$ was greater than 10,000 mg/kg. |
| ***Data Quality*** | Valid without restriction – Klimisch Code 1a |
| ***Reference*** | Mallory, V.T. 1983. Acute oral toxicity study in rats: fatty acid [product name deleted]. Study No. PH 402-AC-009-83. Pharmakon Research International, Inc., Waverly, Pennsylvania. |

| **ACUTE TOXICITY – ORAL** | |
|---|---|
| ***Test substance*** | |
| Chemical Name | Fatty acids, C16-C18 and C18 unsaturated, branched and linear, sodium salt |
| CAS # | Not assigned |
| Remarks | This non-HPV substance is also referred to as monomer acid sodium salt in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | Test procedure was OECD Test Method 423, *"Acute Oral Toxicity- Acute Toxic Class Method"* |
| GLP (Y/N) | Y |
| Year (Study Performed) | 2002 |
| Species | Rat |
| Strain | Sprague-Dawley |
| Route of administration | Oral |
| Dose levels | 2000 mg/kg |
| Sex and number/group | 3 male and 3 female rats |
| Frequency of treatment | Single oral gavage |
| Duration of test | 14 day observation post-treatment |
| Control group (Y/N) | N |

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|---|---|
| ***Result*** | |
| Acute Oral $LD_{50}$ | >2500 mg/kg |
| ***Detailed Summary*** | Sprague-Dawley rats (n = 3/sex) received a single oral (gavage) dose of 2000 mg/kg of monomer acid, sodium salt and were observed for 14 days. Parameters evaluated included clinical signs, mortality, body weight, and gross pathology. None of the animals died. No body weight effects were observed. Gross necropsy revealed no treatment-related effects. The acute oral $LD_{50}$ was estimated as being greater than 2500 mg/kg. |
| ***Data Quality*** | Valid without restriction – Klimisch Code 1a |
| ***Reference*** | Sanders, A. 2002. Acute oral toxicity study in the rat – Acute Toxic Class Method. Project No. 1078/031. SafePharm Laboratories, Derby, UK. |

| **ACUTE TOXICITY – ORAL** | |
|---|---|
| ***Test substance*** | |
| Chemical Name | Fatty acids, C16-C18 and C18 unsaturated, branched and linear, calcium salt |
| CAS # | Not assigned |
| Remarks | This non-HPV substance is also referred to as monomer acid calcium salt in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | Test procedure was OECD Test Method 423, *"Acute Oral Toxicity- Acute Toxic Class Method"* |
| GLP (Y/N) | Y |
| Year (Study Performed) | 2002 |
| Species | Rat |
| Strain | Sprague-Dawley |
| Route of administration | Oral |
| Dose levels | 2000 mg/kg |
| Sex and number/group | 3 male and 3 female rats |
| Frequency of treatment | Single oral gavage |
| Duration of test | 14 day observation post-treatment |
| Control group (Y/N) | N |
| ***Result*** | |
| Acute Oral $LD_{50}$ | >2500 mg/kg |
| ***Detailed Summary*** | Sprague-Dawley rats (n = 3/sex) received a single oral (gavage) dose of 2000 mg/kg of monomer acid, calcium salt and were observed for 14 days. Parameters evaluated included clinical signs, mortality, body weight, and gross pathology. None of the animals died. No body weight effects were observed. Gross necropsy revealed no treatment-related effects. The acute oral $LD_{50}$ was estimated as being greater than 2500 mg/kg. |
| ***Data Quality*** | Valid without restriction – Klimisch Code 1a |
| ***Reference*** | Sanders, A. 2002. Acute oral toxicity study in the rat – Acute Toxic Class Method. Project No. 1078/031. SafePharm Laboratories, Derby, UK. |

| REPEAT DOSE TOXICITY | |
|---|---|
| ***Test substance*** | |
| Chemical Name | Tall oil fatty acid |
| CAS # | 61790-12-3 |
| Remarks | This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | Test procedure was similar to OECD Test Method 407*, "Repeat Dose 28-Day Oral Toxicity Study in Rodents,"* but failed to collect data on several parameters (hematology, clinical chemistry, histopathology) and was only conducted in male animals. |
| Year | 1969 |
| GLP (Y/N) | N (pre-GLP) |
| Species | Rat |
| Strain | Sprague-Dawley |
| Sex | Male |
| Route of Administration | Oral, diet |
| Exposure Period | 28 days |
| Frequency of Treatment | Daily |
| Post-exposure observation period | None |
| Dose Levels | 0, 15, 30, and 60% of total calories |
| Control group (Y/N) | Y |
| ***Results*** | |
| NOAEL: | 15% |
| ***Detailed Summary*** | Male Sprague-Dawley rats (n = 10/group) were fed diets containing tall oil acid distillate (CAS #61790-12-3) as 0, 15, 30 or 60% of the total calories for four weeks. Parameters evaluated included mortality, body weight, and food consumption. One animal treated with 15% died (day of death not specified) and all animals treated with 60% died within four days of dose initiation. It is unlikely that this single death was a treatment related effect since similar mortality did not occur at 30%. No effect on growth rate was reported at 15%, but a significant decrease in growth was reported at 30%. |
| ***Data Quality*** | Not assignable – Klimisch Code 4b |
| ***Reference*** | Seppanen 1969 as cited in: Anon. 1989. Final report on the safety assessment of tall oil acid. J. Amer. Coll. Toxicol. 8:769-776. |

| REPEAT DOSE TOXICITY | |
|---|---|
| ***Test substance*** | |
| Chemical Name | Tall oil fatty acid |
| CAS # | 61790-12-3 |
| Remarks | This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | Test procedure is consistent with OECD Test Method 407, *"Repeat Dose 28-Day Oral Toxicity Study in Rodents"* |
| Year | 1969 |
| GLP (Y/N) | N (pre-GLP) |
| Species | Rat |

| | |
|---|---|
| Strain | Charles River |
| Sex | Male, female |
| Route of Administration | Oral, diet |
| Exposure Period | 90 days |
| Frequency of Treatment | Daily |
| Post-exposure observation period | None |
| Dose Levels | 5, 10, and 25% (approximately equivalent to 2500, 5000, and 12,500 mg/kg/day) |
| Control group (Y/N) | Y |
| ***Results*** | |
| NOEL: | 5%, approximately 2500 mg/kg/day |
| ***Detailed Summary*** | Tall oil fatty acid was administered to Charles River rats (n = 10/sex/group) in the diet at concentrations 0, 5, 10, or 25% for 90 days. The approximate doses were 0, 2,500, 5,000, or 12,500 mg/kg/day, based on standard conversion factors provided by WHO (1990). Parameters evaluated included clinical signs, mortality, body weight, body weight gain, food consumption, hematology, clinical chemistry, urinalysis, gross pathology, organ weights (liver, kidneys, spleen, gonads, heart, adrenal glands, thyroid gland, brain), and microscopic pathology (esophagus, stomach, small intestine, cecum, colon, liver, kidneys, spleen, pancreas, urinary bladder, pituitary gland, adrenal gland, testes, seminal vesicle, ovary, bone marrow, thyroid gland, parathyroid gland, salivary gland, prostate gland, heart, aorta, lung, lymph node, skeletal muscle, peripheral nerve, bone, spinal cord, uterus, trachea, eye, optic nerve, brain).<br><br>Two control rats died during blood sampling. No other deaths occurred and no clinical signs were observed. Body weight and body weight gain were not affected by treatment, but food consumption was slightly decreased at 10 and 25%. No changes in hematology, clinical chemistry or urinalysis parameters occurred at any dose. At gross pathology, no treatment-related effects were noted at any dose. No consistent organ weight changes and no histopathological effects were reported at any dose. Based on these data, the NOEL was 5% (approximately 2,500 mg/kg/day). |
| ***Data Quality*** | Valid without restriction – Klimisch Code 1b |
| ***References*** | Fancher, O.E. 1969. Ninety-day subacute oral toxicity of [trade name deleted; tall oil fatty acid] in albino rats. IBT No. B7067. Industrial Bio-Test Laboratories, Inc., Northbrook, Illinois.<br><br>World Health Organization (WHO). 1990. Principles for the Toxicological Assessment of Pesticide Residues in Food. |

| **IN VITRO GENETIC TOXICITY** | |
|---|---|
| ***Test substance*** | |
| Chemical Name | Tall oil fatty acid |
| CAS # | 61790-12-3 |
| Remarks | This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | Test was consistent with OECD Test Method 471, *"Bacterial* |

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|---|---|
| | *Reverse Mutation Test"* |
| Year | 1984 |
| GLP (Y/N) | Y |
| System of testing | *S. typhimurium* strains TA98, TA100, TA1535, TA1537, TA1538 |
| Concentration | 0, 100, 333, 1000, 3333, 10000 μg/plate |
| Metabolic activation | With and without addition of S-9 fraction from Aroclor 1254-treated Sprague-Dawley rats. |
| ***Results*** | Non-mutagenic |
| ***Detailed Summary*** | Tall oil fatty acid was tested against *S. typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 for mutagenic activity. The test article was tested at concentrations of 100, 333, 1000, 3333 and 10,000 μg/plate with and without metabolic activation with S-9 fraction. Positive controls not requiring metabolic activation included sodium azide, 9-aminoacridine and 2-nitrofluorene; the positive control requiring metabolic activation was 2-aminoanthracene. No increases in mutation frequency were reported at any concentration of tall oil fatty acid with or without metabolic activation. Tall oil fatty acid was not mutagenic in this assay. |
| ***Data Quality*** | Valid without restriction – Klimisch Code 1a |
| ***Reference*** | Godek, E.G. 1983. Ames Salmonella/microsome plate test: fatty acid [trade name deleted]. Study No. PH 301D-AC-018-83. Pharmakon Research International, Inc., Waverly, Pennsylvania. |

| **IN VITRO GENETIC TOXICITY** | |
|---|---|
| ***Test substance*** | |
| Chemical Name | Fatty acids, C16-C18 and C18 unsaturated, branched and linear, sodium salt |
| CAS # | Not assigned |
| Remarks | This substance is also referred to as monomer acid sodium salt in the Final Summary document for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | OECD Test Method 471, *"Bacterial Reverse Mutation Test"* |
| Year | 2002 |
| GLP (Y/N) | Y |
| System of testing | *S. typhimurium* strains TA98, TA100, TA102, TA1535 and TA15378 |
| Concentration | 50, 150, 500, 1500, and 5000 μg/plate |
| Metabolic activation | With and without addition of S-9 fraction from phenobarbitone/â-naphthoflavone-treated Sprague-Dawley rats. |
| ***Results*** | Non-mutagenic with or without metabolic activation |
| ***Detailed Summary*** | Monomer acid sodium salt was tested against *S. typhimurium* strains TA98, TA100, TA102, TA1535 and TA1537 for mutagenic activity at concentrations of 50, 150, 500, 1500 and 5000 μg/plate with and without metabolic activation. Positive controls not requiring metabolic activation included N-ethyl-N-nitro-N-nitrosoguanidine, mytomycin C, , 4-nitroquinoline-1-oxide and 9-aminoacridine; the positive controls requiring metabolic activation were 2-aminoanthracene, benzo(a)pyrene, and 1,8-dihydroxyanthraquinone. No increases in mutation frequency were reported at any concentration of monomer acid sodium salt with or without metabolic activation. Monomer acid sodium salt |

| | |
|---|---|
| | was not mutagenic in this assay either with or without metabolic activation. |
| ***Data Quality*** | Valid without restriction – Klimisch Code 1a |
| ***Reference*** | Thompson, P.W. 2002. [Monomer Acid Sodium Salt] Reverse Mutation Assay "Ames Test" Using *Salmonella Typhimurium*. Proj. No. 1078/038. SafePharm Laboratories, Derby, UK. |

| **IN VITRO GENETIC TOXICITY** | |
|---|---|
| ***Test substance*** | |
| Chemical Name | Tall oil fatty acid |
| CAS # | 61790-12-3 |
| Remarks | This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | OECD Test Method 473, *"Chromosomal Aberration Assay with Chinese Hamster Ovary Cells in vitro."* |
| Year | 2001 |
| GLP (Y/N) | Y |
| System of testing | Chinese Hamster Ovary (CHO) cells *in vitro* |
| Concentration | With S9 mix: 5, 10 and 20 ug/ml<br>Without S9 mix: 39, 78 and 156 ug/ml |
| Metabolic activation | With and without addition of S-9 fraction from Aroclor 1254-treated adult male Fisher rats. |
| ***Results*** | Clastogenic with S9 mix at 20 ug/ml and without S9 mix at 156 ug/ml; both concentrations were overtly toxic to the cells. |
| ***Detailed Summary*** | Tall oil fatty acid was tested in Chinese hamster ovary (CHO) cells for clastogenic activity both with and with metabolic activation with rat liver S9 mix. The test article was tested with metabolic activation with S9 mix at concentrations of 5, 10 and 20 ug/ml and without metabolic activation with S9 mix at concentrations of 39, 78 and 156 ug/ml. The positive controls requiring and not requiring metabolic activation were cyclophosphamide (CPH) and methanesulphonate (MMS), respectively. Treatments with test item or controls were performed on duplicate cell cultures. Two slides per culture up to 50 metaphase cells per slide were examined. A dose level was considered to be toxic if the cell count was reduced to less than 50% of the mean vehicle control values or if consistent evidence of changes to cell morphology was observed. In both the presence and absence of S9 mix, positive levels of structural aberrations were observed. In the presence of S9 mix, this response was observed in the cultures treated with 20 ug/ml and in the absence of S9 mix, in the cultures treated with 156 ug/ml. Both of these concentrations were judged overtly toxic to the cultures. Therefore, tall oil fatty acid was a clastogen at toxic concentrations. |
| ***Data Quality*** | Valid without restriction – Klimisch Code 1a |
| ***Reference*** | Murie, E. 2001. Fatty Acids, CAS No. 61790-12-3 Chromosomal Aberration Assay with Chinese Hamster Ovary Cells in vitro (Complying with EC (Annex V) and OECD 473 Guidelines). Report No. 20712. Inveresk Research, Tranent, Scotland. |

| **IN VITRO GENETIC TOXICITY** | |
|---|---|
| ***Test substance*** | |
| Chemical Name | Fatty acids, C16-C18 and C18 unsaturated, branched and linear, calcium salt |
| CAS # | Not assigned |
| Remarks | This substance is also referred to as monomer acid calcium salt in the Final Summary document for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | OECD Test Method 473, *"Genetic Toxicology: Chromosomal Aberration Test."* |
| Year | 2002 |
| GLP (Y/N) | Y |
| System of testing | Human lymphocytes *in vitro* |
| Concentration | With S9 mix: 0, 31.25, 62.5, 125, 250, 375 and 500 ug/ml<br>Without S9 mix: 0, 31.25, 62.5, 125, 250, 375 and 500 ug/ml |
| Metabolic activation | With and without addition of S-9 fraction from phenobarbitone/â-naphthoflavone-treated male Sprague-Dawley rats. |
| ***Results*** | Monomer acid calcium salt was non-clastogenic to human lymphocytes *in vitro* both with and without metabolic activation. |
| ***Detailed Summary*** | Monomer acid calcium salt was tested *in vitro* in human lymphocyrtes for clastogenic activity both with and with metabolic activation with rat liver S9 mix. Lymphocytes were obtained from a volunteer who had been previously sereened for suitability (not exposed to radiation, hazardous chemicals or recently suffereing from a viral infection). Cells were grown in Eagle's minimal essential medium with HEPES buffer, supplemented with L-glutamine, penicillin/streptomycin, amphotericin B and 15% fetal calf serum. Following a preliminary toxicity rangefinding test, the test article was tested both with and without metabolic activation with S9 mix at concentrations of 0, 31.25, 62.5, 125, 250, 375 and 500 ug/ml. The positive controls requiring and not requiring metabolic activation were cyclophosphamide and mitomycin C, respectively. A total of 2000 lymphocyte cell nuclei were counted and the number of cells in metaphase recorded and expressed as the mitotic indec and as a percentage of the vehicle control value. Due to cellular toxicity the maximum dose level selected for metaphase analysis was 150 ug/ml in both exposure groups. The test material did not induce a toxicologically significant increase in the frequency of cells with chromosomal aberrations in either the absence or presence of a liver enzyme metabolizing system in either of two separate experiments. Monomer acid calcium salt was therefore considered to be non-clastogenic to human lymphocytes *in vitro.* |
| ***Data Quality*** | Valid without restriction – Klimisch Code 1a |
| ***Reference*** | Jenkinson, P.C. and Durward, R. 2002. [Monomer acid calcium salt] Chromosomal Aberration Test in Human Lymphocytes *In* Vitro. SPL Proj. No. 1078/086. SafePharm Laboratories, Derby, UK. |

| REPRODUCTION AND DEVELOPMENTAL TOXICITY | |
|---|---|
| ***Test substance*** | |
| Chemical Name | Tall oil fatty acid |
| CAS # | 61790-12-3 |
| Remarks | This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | Test procedure was consistent with OECD Test Method 416, *"Two-Generation Reproduction Toxicity Study"* with one exception: the initial treatment period was decreased (three weeks versus ten weeks). |
| Year | 1975 |
| GLP (Y/N) | N |
| Species | Rat |
| Strain | Sprague-Dawley |
| Sex | Male and female |
| Route of Administration | Oral, diet |
| Frequency of Treatment | Daily |
| Dose | 5 and 10% (approximately equivalent to 2500 and 5000 mg/kg/day) |
| Control group (Y/N) | Y |
| Pre-mating exposure period for males | 20 days (parental generation) |
| Pre-mating exposure period for females | 20 days (parental generation) |
| ***Results*** | |
| NOEL | 10%, approximately 5000 mg/kg/day, for reproductive and systemic toxicity |
| ***Detailed Summary*** | Sprague-Dawley rats (n = 30 females/group and 15 males/group) were administered tall oil fatty acid (CAS #61790-12-3) in the diet at concentrations of 0, 5 or 10%. The approximate doses were 0, 2,500, or 5,000 mg/kg/day, based on standard conversion factors provided by WHO (1990). The parental ($F_0$) generation began treatment at 80 days of age and were mated at 100 days of age. Treatment continued through the weaning of the first generation ($F_1$). After weaning, 20 $F_1$ males and 20 $F_1$ females per group were maintained on the parental diet. At 100 days of age, these rats were mated and allowed to deliver pups ($F_2$). Parameters evaluated included $F_1$ reproductive parameters, $F_1$ fertility, viability, lactation, and gestation indices, hematology, serum chemistry, urinalysis, and microscopic pathology of the $F_2$ pups (brain, pituitary gland, spinal cord, eye, sub-maxillary gland, thyroid, lungs, heart, liver, kidneys, spleen, adrenals, pancreas, stomach, intestines, lymph nodes, bladder, gonads, skin, bone, bone marrow, nerve, muscle).<br><br>Treatment did not affect the number of liveborn or stillborn $F_1$ litters and pups, or $F_1$ weaning weight. No treatment-related changes in fertility, viability, lactation, or gestation indices were measured. Hematology, clinical chemistry and urinalysis parameters were similarly unchanged, and gross and microscopic pathology revealed no treatment-related effects. Tall oil fatty acid had no effect on the reproductive or developmental capabilities of rats at doses as high as 10% (approximately 5,000 mg/kg/day). |

| | |
|---|---|
| ***Data Quality*** | Valid without restriction – Klimisch Code 1b |
| ***References*** | Tegeris, A.S. 1975. Sub-acute reproduction in the rat on tall oil fatty acid [trade name deleted]. Report No. 75-106. Pharmacopathics Research Laboratories, Inc., Laurel, Maryland.<br><br>World Health Organization (WHO). 1990. Principles for the Toxicological Assessment of Pesticide Residues in Food. |

| **REPRODUCTION AND DEVELOPMENTAL TOXICITY** | |
|---|---|
| ***Test substance*** | |
| Chemical Name | Tall oil fatty acid |
| CAS # | 61790-12-3 |
| Remarks | This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances. |
| ***Method*** | |
| Method/Guideline followed | Test procedure was consistent with OECD Test Method 416, *"Two-Generation Reproduction Toxicity Study"* with one exception: the initial treatment period was decreased (three weeks versus ten weeks). |
| Year | 1977 |
| GLP (Y/N) | N |
| Species | Rat |
| Strain | Sprague-Dawley |
| Sex | Male and female |
| Route of Administration | Oral, diet |
| Frequency of Treatment | Daily |
| Dose | 5 and 10% (approximately equivalent to 2500 and 5000 mg/kg/day) |
| Control group (Y/N) | Y |
| Pre-mating exposure period for males | 20 days (parental generation) |
| Pre-mating exposure period for females | 20 days (parental generation) |
| ***Results*** | |
| NOEL | 10%, approximately 5000 mg/kg/day, for reproductive and systemic toxicity |
| ***Detailed Summary*** | Sprague-Dawley rats (n = 30 females/group and 15 males/group) were administered tall oil fatty acid (CAS #61790-12-3) in the diet at concentrations of 0, 5 or 10%. The approximate doses were 0, 2,500, or 5,000 mg/kg/day, based on standard conversion factors provided by WHO (1990). The parental ($F_0$) generation began treatment at 80 days of age and were mated at 100 days of age. Treatment continued through the weaning of the first generation ($F_1$). After weaning, 20 $F_1$ males and 20 $F_1$ females per group were maintained on the parental diet. At 100 days of age, these rats were mated and were allowed to deliver pups ($F_2$). The $F_2$ generation survived to weaning. Parameters evaluated included $F_1$ reproductive parameters, $F_1$ fertility, viability, lactation, and gestation indices, hematology, serum chemistry, urinalysis, organ weights for $F_1$ animals (thyroids, heart, liver, adrenals, kidneys, gonads), gross pathology of $F_1$ and $F_2$ animals, and microscopic pathology of the $F_2$ pups (brain, pituitary gland, spinal cord, eye, sub-maxillary gland, thyroid, lungs, heart, liver, kidneys, spleen, |

| | |
|---|---|
| | adrenals, pancreas, stomach, intestines, lymph nodes, bladder, gonads, skin, bone, bone marrow, nerve, muscle).<br><br>There were no treatment effects on reproductive performance, the number of liveborn or stillborn $F_1$ litters and pups, or weaning weight of the $F_1$ pups. No treatment-related changes in fertility, viability, lactation, or gestation indices were measured. Hematology, clinical chemistry and urinalysis parameters were similarly unchanged, organ weights were unchanged, and gross and microscopic pathology revealed no treatment-related effects. Tall oil fatty acid had no effect on the reproductive or developmental capabilities of rats at doses as high as 10% (approximately 5,000 mg/kg/day). |
| ***Data Quality*** | Valid without restriction – Klimisch Code 1b |
| ***References*** | Tegeris, A.S. 1977. Tall oil fatty acid: two-generation reproduction study in the rat. Report No. 77-124. Pharmacopathics Research Laboratories, Inc., Laurel, Maryland.<br><br>World Health Organization (WHO). 1990. Principles for the Toxicological Assessment of Pesticide Residues in Food. |

# I U C L I D

# D a t a s e t

| | |
|---|---|
| **Existing Chemical** | Substance ID: 61790-12-3 |
| **CAS No.** | 61790-12-3 |
| **EINECS Name** | Fatty acids, tall-oil |
| **EINECS No.** | 263-107-3 |
| **Molecular Formula** | <no data> |

**Dataset created by:** EUROPEAN COMMISSION - European Chemicals Bureau

**This dossier is a compilation based on data reported by the European Chemicals Industry following 'Council Regulation (EEC) No. 793/93 on the Evaluation and Control of the Risks of Existing Substances'. All (non-confidential) information from the single datasets, submitted in the IUCLID/HEDSET format by individual companies, was integrated to create this document.**

**The data have not undergone any evaluation by the European Commission.**

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**Chapters:** all

**Edition:** Year 2000 CD-ROM edition

**Flags:** non-confidential

## 1.0.1 OECD and Company Information

**Name:** BASF AG
**Street:** Karl-Bosch-Str
**Town:** 67056 Ludwigshafen
**Country:** Germany

**Name:** Bärlocher Italia S.p.A.
**Street:** Via San Colombano 62/A
**Town:** 26900 Lodi (Mi)
**Country:** Italy
**Phone:** 0371/451-1
**Telefax:** 0371/30650

**Name:** CYTEC INDUSTRIES B.V.
**Street:** P.O.Box 5195 , Botlekweg 175
**Town:** 3197 ZH Rotterdam
**Country:** Netherlands

**Name:** DSM Resins BV
**Street:** Ceintuurbaan 5
**Town:** 8022 AW Zwolle
**Country:** Netherlands
**Phone:** 038 4569569
**Telefax:** 038 4569500

**Name:** FORCHEM OY
**Street:** Nuottasaarenkatu 24, P.O.Box 165
**Town:** FIN-90101 OULU
**Country:** Finland
**Phone:** +358-81-3163100
**Telefax:** +358-81-3163101
**Telex:** 32125

**Name:** g.c.rutteman & co. b.v
**Street:** postbus 30028
**Town:** 3001 da rotterdam
**Country:** Netherlands
**Phone:** 010-4139490
**Telefax:** 010-4144781

**Name:** Hickson Coatings Italia S.p.A
**Street:** Via del Fiffo, 12-CP. 18
**Town:** 40065 Pianoro
**Country:** Italy
**Phone:** +39 51 77 72 11
**Telefax:** +39 51 77 74 37

**Name:** Krems Chemie AG
**Street:** Hafenstrasse 77
**Town:** A-3500 Krems
**Country:** Austria

**Name:** Krems Chemie Aktiengesellschaft
**Street:** Hafenstrasse 77
**Town:** A-3500 KREMS
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**Phone:** +43-2732-899/254
**Telefax:** +43-2732-899/302
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**Name:** LES DERIVES RESINIQUES ET TERPENIQUES
**Street:** 30, rue Gambetta
**Town:** 40105 DAX
**Country:** France
**Phone:** 58-56-62-00
**Telefax:** 58-56-62-40
**Telex:** 560095

**Name:** Steyrermühl AG
**Street:** Fabriksplatz 1
**Town:** 4662 Steyrermühl
**Country:** Austria
**Phone:** 07613/8900-509
**Telefax:** -357

**Name:** Union Camp Chemicals
**Street:** Vigo Lane Chester le Street
**Town:** DH3 2RB CO Durham
**Country:** United Kingdom
**Phone:** (44) 1.914.102.631
**Telefax:** (44)1.914.109.391

## 1.0.2 Location of Production Site

-

## 1.0.3 Identity of Recipients

-

## 1.1 General Substance Information

**Substance type:** natural substance
**Physical status:** liquid

**Substance type:** organic
**Physical status:** liquid

## 1.1.1 Spectra

-

## 1.2 Synonyms

A-Tall FA-XA
**Source:** BASF AG Ludwigshafen

Acides gras de Tall Oil
**Source:** LES DERIVES RESINIQUES ET TERPENIQUES DAX

Acintol D 30RL
**Source:** BASF AG Ludwigshafen

Acintol D 30RL Pamak 4
**Source:** Union Camp Chemicals Durham

Acintol EPG
**Source:** BASF AG Ludwigshafen

Acintol FA 1
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Acintol FA 2
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Acintol FA 3
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Actinol FA 2
**Source:** BASF AG Ludwigshafen

Bevacid 2
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Crofatol P
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Disproportionated tall oil fatty acid
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Emtall 729
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Etol FA-X
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

FA 1
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Fatty acids
**Source:** Union Camp Chemicals Durham

Fatty acids, tall-oil
**Source:** BASF AG Ludwigshafen

Fatty acids, tall-oil, disproportionated
**Source:** BASF AG Ludwigshafen

Fettsäure
**Source:** Krems Chemie AG Krems

Hartall F 1
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Hartall FA 1
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Hartall FA 20
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

L 1AS
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

L 5
**Source:** Union Camp Chemicals Durham

L 5 (fatty acid)
**Source:** BASF AG Ludwigshafen

Liqro W
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Neo-fat 42-06
**Source:** BASF AG Ludwigshafen

neo-Fat 42-12
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Neo-fat 42-12
**Source:** BASF AG Ludwigshafen

neo-Fat 42-6
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

neo-Fat 42-70
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Neo-fat 42-70
**Source:** BASF AG Ludwigshafen

Olein
**Source:** Krems Chemie AG Krems

Pamak 1
**Source:** BASF AG Ludwigshafen

Pamak 4
**Source:** BASF AG Ludwigshafen

Pamak 4A
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Pamak I
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Pamolyn 125
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Sylfat 94
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Sylfat 96
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Sylfat V 18
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Talacyd D 50
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Talacyd P 40
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Talacyd P 50
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Talacyd T 2
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Tall Fax 250
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Tall oil acids
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

tall oil fatty acid
**Source:** g.c.rutteman & co. b.v rotterdam

Tall oil fatty acids.
**Source:** Hickson Coatings Italia S.p.A Pianoro

Tall-oil fatty acids
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Tall-oil, disproportionated
**Source:** Union Camp Chemicals Durham

Tallölfettsäure
**Source:** Krems Chemie AG Krems

TOFA
**Source:** DSM Resins BV Zwolle

Unitol AC
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Unitol ACD
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Unitol BKS
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Unitol DSR
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Unitol DSR 90
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Unitol DSR 90, Hartall FA 1, L 1AS, L 5, Unitol AC, OULU 102, VALKE TOFA 2
**Source:** FORCHEM OY OULU

Unitol LFA
**Source:** Union Camp Chemicals Durham
BASF AG Ludwigshafen

Westvaco 1480
**Source:** BASF AG Ludwigshafen

## 1.3 Impurities

-

## 1.4 Additives

-

## 1.5 Quantity

**Quantity** 100 000 - 500 000 tonnes

## 1.6.1 Labelling

-

## 1.6.2 Classification

-

## 1.7 Use Pattern

**Type:** type
**Category:** Non dispersive use

**Type:** industrial
**Category:** Basic industry: basic chemicals

**Type:** industrial
**Category:** Chemical industry: used in synthesis

**Type:** industrial
**Category:** Paints, lacquers and varnishes industry

**Type:** industrial
**Category:** Paper, pulp and board industry

**Type:** use
**Category:** Intermediates

## 1.7.1 Technology Production/Use

-

## 1.8 Occupational Exposure Limit Values

**Type of limit:**
**Limit value:**
**Remark:** No Exposure Limit Value assigned.
**Source:** Hickson Coatings Italia S.p.A Pianoro

**Type of limit:**
**Limit value:**
**Remark:** No data available.
**Source:** Union Camp Chemicals Durham

## 1.9 Source of Exposure

**Remark:** Substance is handled in a semi-closed system for the manufacture of resins used in the production of surface coatings.
**Source:** Hickson Coatings Italia S.p.A Pianoro

**Remark:** The human or environmental exposure to the substance, other than in the workplace or indoor environment, is anticipated to be minimal based upon knowledge of the manufacturing process and practice.
**Source:** Union Camp Chemicals Durham

**Remark:** The human or environmental exposure to the substance, other than in the worklace or indoor environment, is anticipated to be minimal based upon knowledge of the manufacturing process and practice.
**Source:** FORCHEM OY OULU

## 1.10.1 Recommendations/Precautionary Measures

-

## 1.10.2 Emergency Measures

-

## 1.11 Packaging

-

## 1.12 Possib. of Rendering Subst. Harmless

-

## 1.13 Statements Concerning Waste

-

## 1.14.1 Water Pollution

-

## 1.14.2 Major Accident Hazards

-

## 1.14.3 Air Pollution

-

## 1.15 Additional Remarks

**Remark:** Substance is transported in road tankers and stored in bulk storages.
**Source:** Hickson Coatings Italia S.p.A Pianoro

## 1.16 Last Literature Search

-

## 1.17 Reviews

-

## 1.18 Listings e.g. Chemical Inventories

-

## 2.1 Melting Point

**Value:**
**Remark:** Not relevant to this liquid substance.
**Source:** Union Camp Chemicals Durham

## 2.2 Boiling Point

**Value:** ca. 160 - 210 degree C at 6.6 hPa
**GLP:** no data
**Source:** Union Camp Chemicals Durham

(1)

## 2.3 Density

**Type:** relative density
**Value:** ca. .9 at 25 degree C
**GLP:** no data
**Source:** Union Camp Chemicals Durham

(1)

## 2.3.1 Granulometry

-

## 2.4 Vapour Pressure

**Value:**
**Remark:** Vapour pressure is negligable at 25 degrees C.
**Source:** Union Camp Chemicals Durham

(1)

## 2.5 Partition Coefficient

**log Pow:** = 4.89 - 5.98 at 25 degree C
**Method:** Directive 84/449/EEC, A.8 "Partition coefficient"
**Year:** 1984
**GLP:** no
**Source:** Union Camp Chemicals Durham

(2)

## 2.6.1 Water Solubility

**Remark:** Virtually insoluble in water.
**Source:** Union Camp Chemicals Durham

(1)

## 2.6.2 Surface Tension

-

## 2.7 Flash Point

**Value:** ca. 194 degree C
**Type:**
**Method:**
**Year:**
**GLP:** no data
**Source:** Union Camp Chemicals Durham

(1)

## 2.8 Auto Flammability

**Value:**
**Remark:** No data available.
**Source:** Union Camp Chemicals Durham

## 2.9 Flammability

**Result:**
**Remark:** Not applicable to this liquid substance.
**Source:** Union Camp Chemicals Durham

## 2.10 Explosive Properties

**Result:**
**Remark:** No data are available relating to the explosivity of the substance. However, experience in use would suggest that the substance does not show explosive properties.
**Source:** Union Camp Chemicals Durham

## 2.11 Oxidizing Properties

**Result:**
**Remark:** No data are available relating to the oxidising properties of the substance. However, experience in use would suggest that the substance is not oxidising.
**Source:** Union Camp Chemicals Durham

## 2.12 Additional Remarks

-

## 3.1.1 Photodegradation

**Type:**
**Method:**
**Year:** **GLP:**
**Test substance:**
**Remark:** A search of the literature via online databases such as the Hazardous Substances Databank and the Registry of Toxic Effects of Chemicals, which contain information on the various properties of chemical substances, revealed no data for this property.
**Source:** Union Camp Chemicals Durham

## 3.1.2 Stability in Water

**Type:**
**Method:**
**Year:** **GLP:**
**Test substance:**
**Remark:** A search of the literature via online databases such as the Hazardous Substances Databank and the Registry of Toxic Effects of Chemicals, which contain information on the various properties of chemical substances, revealed no data for this property.
**Source:** Union Camp Chemicals Durham

## 3.1.3 Stability in Soil

**Type:** **Radiolabel:**
**Concentration:**
**Cation exch. capac.**
**Microbial biomass:**
**Method:**
**Year:** **GLP:**
**Test substance:**
**Remark:** A search of the literature via online databases such as the Hazardous Substances Databank and the Registry of Toxic Effects of Chemicals, which contain information on the various properties of chemical substances, revealed no data for this property.
**Source:** Union Camp Chemicals Durham

## 3.2 Monitoring Data (Environment)

**Type of measurement:**
**Medium:**
**Remark:** A search of the literature via online databases such as the Hazardous Substances Databank and the Registry of Toxic Effects of Chemicals, which contain information on the various properties of chemical substances, revealed no data.
**Source:** Union Camp Chemicals Durham

## 3.3.1 Transport between Environmental Compartments

**Type:**
**Media:**
**Method:**
**Year:**
**Remark:** A search of the literature via online databases such as the Hazardous Substances Databank and the Registry of Toxic Effects of Chemicals, which contain information on the various properties of chemical substances, revealed no data for this property.
**Source:** Union Camp Chemicals Durham

## 3.3.2 Distribution

**Media:**
**Method:**
**Year:**
**Remark:** A search of the literature via online databases such as the Hazardous Substances Databank and the Registry of Toxic Effects of Chemicals, which contain information on the various properties of chemical substances, revealed no data for this property.
**Source:** Union Camp Chemicals Durham

## 3.4 Mode of Degradation in Actual Use

**Remark:** The substance is anticipated to degrade via Biodegradation under environmental conditions.
**Source:** Union Camp Chemicals Durham

## 3.5 Biodegradation

**Type:** aerobic
**Inoculum:** activated sludge, domestic
**Concentration:** 10 mg/l related to DOC (Dissolved Organic Carbon)
**Degradation:** = 74 % after 28 day
**Result:** readily biodegradable
**Kinetic:**

| | |
|---|---|
| 1 day | = 4 % |
| 3 day | = 20 % |
| 10 day | = 62 % |
| 20 day | = 73 % |
| 28 day | = 74 % |

**Method:** Directive 84/449/EEC, C.5 "Biotic degradation - modified Sturm test"
**Year:** 1984 **GLP:** no
**Test substance:** as prescribed by 1.1 - 1.4
**Source:** Union Camp Chemicals Durham

(3)

## 3.6 BOD5, COD or BOD5/COD Ratio

**Remark:** No data available.
**Source:** Union Camp Chemicals Durham

## 3.7 Bioaccumulation

**Species:**
**Exposure period:**
**Concentration:**
**BCF:**
**Elimination:**
**Method:**
**Year:** **GLP:**
**Test substance:**
**Remark:** A search of the literature via online databases such as the Hazardous Substances Databank and the Registry of Toxic Effects of Chemicals, which contain information on the various properties of chemical substances, revealed no data for this property.
**Source:** Union Camp Chemicals Durham

## 3.8 Additional Remarks

-

## AQUATIC ORGANISMS

### 4.1 Acute/Prolonged Toxicity to Fish

**Type:** semistatic
**Species:**
**Exposure period:** 96 hour(s)
**Unit:** mg/l **Analytical monitoring:** yes
**NOEC:** >= 1000
**LC0:** >= 1000
**LC50:** >= 1000
**LC100:** >= 1000
**Method:** Directive 84/449/EEC, C.1 "Acute toxicity for fish"
**Year:** 1984 **GLP:** no
**Test substance:** as prescribed by 1.1 - 1.4
**Source:** Union Camp Chemicals Durham
**Test substance:** A water accommodated fraction of the test substance was used in the study.

(4)

### 4.2 Acute Toxicity to Aquatic Invertebrates

**Species:** Daphnia magna (Crustacea)
**Exposure period:** 48 hour(s)
**Unit:** mg/l **Analytical monitoring:** yes
**NOEC:** >= 1000
**EC0:** >= 1000
**EC50:** >= 1000
**EC100:** >= 1000
**Method:** Directive 84/449/EEC, C.2 "Acute toxicity for Daphnia"
**Year:** 1984 **GLP:** no
**Test substance:** as prescribed by 1.1 - 1.4
**Source:** Union Camp Chemicals Durham
**Test substance:** A water accommodated fraction of the test substance was used in the study.

(5)

## 4.3 Toxicity to Aquatic Plants e.g. Algae

**Species:** Selenastrum capricornutum (Algae)
**Endpoint:**
**Exposure period:** 72 hour(s)
**Unit:** mg/l **Analytical monitoring:** yes
**NOEC:** >= 1000
**LOEC:** >= 1000
**EC0:** >= 1000
**EC10:** >= 1000
**EC50:** >= 1000
**Method:** Directive 87/302/EEC, part C, p. 89 "Algal inhibition test"
**Year:** 1987 **GLP:** no
**Test substance:** as prescribed by 1.1 - 1.4
**Source:** Union Camp Chemicals Durham
**Test substance:** A water accommodated fraction of the test substance was used in the study.

(6)

## 4.4 Toxicity to Microorganisms e.g. Bacteria

**Type:**
**Species:**
**Exposure period:**
**Unit:** **Analytical monitoring:**
**Method:**
**Year:** **GLP:**
**Test substance:**
**Remark:** Biodegradation occured to a significant extent in the ready biodegradability test. Therefore the substance cannot be unduly toxic to sewage micro-organisms.
**Source:** Union Camp Chemicals Durham

## 4.5 Chronic Toxicity to Aquatic Organisms

### 4.5.1 Chronic Toxicity to Fish

**Species:**
**Endpoint:**
**Exposure period:**
**Unit:** **Analytical monitoring:**
**Method:**
**Year:** **GLP:**
**Test substance:**
**Remark:** A search of the literature via online databases such as the Hazardous Substances Databank and the Registry of Toxic Effects of Chemicals, which contain information on the various properties of chemical substances, revealed no data for this property.
**Source:** Union Camp Chemicals Durham

### 4.5.2 Chronic Toxicity to Aquatic Invertebrates

**Species:**
**Endpoint:**
**Exposure period:**
**Unit:** **Analytical monitoring:**
**Method:**
**Year:** **GLP:**
**Test substance:**
**Remark:** A search of the literature via online databases such as the Hazardous Substances Databank and the Registry of Toxic Effects of Chemicals, which contain information on the various properties of chemical substances, revealed no data for this property.
**Source:** Union Camp Chemicals Durham

## TERRESTRIAL ORGANISMS

### 4.6.1 Toxicity to Soil Dwelling Organisms

**Type:**
**Species:**
**Endpoint:**
**Exposure period:**
**Unit:**
**Method:**
**Year:** **GLP:**
**Test substance:**
**Remark:** A search of the literature via online databases such as the Hazardous Substances Databank and the Registry of Toxic Effects of Chemicals, which contain information on the various properties of chemical substances, revealed no data for this property.
**Source:** Union Camp Chemicals Durham

### 4.6.2 Toxicity to Terrestrial Plants

**Species:**
**Endpoint:**
**Expos. period:**
**Unit:**
**Method:**
**Year:** **GLP:**
**Test substance:**
**Remark:** A search of the literature via online databases such as the Hazardous Substances Databank and the Registry of Toxic Effects of Chemicals, which contain information on the various properties of chemical substances, revealed no data for this property.
**Source:** Union Camp Chemicals Durham

## 4.6.3 Toxicity to other Non–Mamm. Terrestrial Species

**Species:**
**Endpoint:**
**Expos. period:**
**Unit:**
**Method:**
**Year:** **GLP:**
**Test substance:**
**Remark:** A search of the literature via online databases such as the Hazardous Substances Databank and the Registry of Toxic Effects of Chemicals, which contain information on the various properties of chemical substances, revealed no data for this property.
**Source:** Union Camp Chemicals Durham

## 4.7 Biological Effects Monitoring

**Remark:** A search of the literature via online databases such as the Hazardous Substances Databank and the Registry of Toxic Effects of Chemicals, which contain information on the various properties of chemical substances, revealed no data for this property.
**Source:** Union Camp Chemicals Durham

## 4.8 Biotransformation and Kinetics

**Type:**
**Remark:** No data available.
**Source:** Union Camp Chemicals Durham

## 4.9 Additional Remarks

-

## 5.1 Acute Toxicity

### 5.1.1 Acute Oral Toxicity

**Type:** LD50
**Species:** rat
**Sex:**
**Number of Animals:**
**Vehicle:**
**Value:** = 74000 mg/kg bw
**Method:**
**Year:** **GLP:** no data
**Test substance:** other TS
**Source:** Union Camp Chemicals Durham
**Test substance:** Fatty acids, Tall oil is a mixture of naturally-occuring fatty acids (90% or more), rosin acids (up to 10% but usually less than 3.5%) and neutrals (unsaponafiables, 3.5% or less).
Toxicity data are given for the components of the mixture.
Record 1 = Oleic acid

(1)

**Type:** LD50
**Species:** rat
**Sex:**
**Number of Animals:**
**Vehicle:**
**Value:** > 3200 mg/kg bw
**Method:**
**Year:** **GLP:** no data
**Test substance:** other TS
**Source:** Union Camp Chemicals Durham
**Test substance:** Fatty acids, Tall oil is a mixture of naturally-occuring fatty acids (90% or more), rosin acids (up to 10% but usually less than 3.5%) and neutrals (unsaponafiables, 3.5% or less).
Toxicity data are given for the components of the mixture.
Record 2 = Linoleic acid

(1)

**Type:** LD50
**Species:** rat
**Sex:**
**Number of Animals:**
**Vehicle:**
**Value:** = 7600 mg/kg bw
**Method:**
**Year:** **GLP:** no data
**Test substance:** other TS
**Source:** Union Camp Chemicals Durham
**Test substance:** Fatty acids, Tall oil is a mixture of naturally-occuring fatty acids (90% or more), rosin acids (up to 10% but usually less than 3.5%) and neutrals (unsaponafiables, 3.5% or less).

Toxicity data are given for the components of the mixture.
Record 3 = Rosin acids

(1)

**Type:** LD50
**Species:** mouse
**Sex:**
**Number of Animals:**
**Vehicle:**
**Value:** = 4600 mg/kg bw
**Method:**
**Year:** **GLP:** no data
**Test substance:** other TS
**Source:** Union Camp Chemicals Durham
**Test substance:** Fatty acids, Tall oil is a mixture of naturally-occuring fatty acids (90% or more), rosin acids (up to 10% but usually less than 3.5%) and neutrals (unsaponafiables, 3.5% or less).
Toxicity data are given for the components of the mixture.
Record 4 = Rosin acids, using mice.

(1)

## 5.1.2 Acute Inhalation Toxicity

**Type:**
**Species:**
**Sex:**
**Number of Animals:**
**Vehicle:**
**Exposure time:**
**Value:**
**Method:**
**Year:** **GLP:**
**Test substance:**
**Remark:** A search of the literature via online databases such as the Hazardous Substances Databank and the Registry of Toxic Effects of Chemicals, which contain information on the various properties of chemical substances, revealed no data for this property.
**Source:** Union Camp Chemicals Durham

## 5.1.3 Acute Dermal Toxicity

**Type:**
**Species:**
**Sex:**
**Number of Animals:**
**Vehicle:**
**Value:**
**Method:**
**Year:** **GLP:**
**Test substance:**
**Remark:** A search of the literature via online databases such as the Hazardous Substances Databank and the Registry of Toxic Effects of Chemicals, which contain information on the various properties of chemical substances, revealed no data for this property.
**Source:** Union Camp Chemicals Durham

## 5.1.4 Acute Toxicity, other Routes

**Type:**
**Species:**
**Sex:**
**Number of Animals:**
**Vehicle:**
**Route of admin.:**
**Value:**
**Method:**
**Year:** **GLP:**
**Test substance:**
**Remark:** A search of the literature via online databases such as the Hazardous Substances Databank and the Registry of Toxic Effects of Chemicals, which contain information on the various properties of chemical substances, revealed no data for this property.
**Source:** Union Camp Chemicals Durham

## 5.2 Corrosiveness and Irritation

## 5.2.1 Skin Irritation

**Species:** rabbit
**Concentration:**

**Exposure:**
**Exposure Time:**
**Number of Animals:**
**PDII:**
**Result:** slightly irritating
**EC classificat.:**
**Method:**
**Year:** **GLP:** no data
**Test substance:** other TS
**Source:** Union Camp Chemicals Durham
**Test substance:** Fatty acids, Tall oil is a mixture of naturally-occuring fatty acids (90% or more), rosin acids (up to 10% but usually less than 3.5%) and neutrals (unsaponafiables, 3.5% or less).
Toxicity data are given for the components of the mixture.
Record 1 = Oleic acid

(1)

**Species:** rabbit
**Concentration:**

**Exposure:**
**Exposure Time:**
**Number of Animals:**
**PDII:**
**Result:** slightly irritating
**EC classificat.:**
**Method:**
**Year:** **GLP:** no data
**Test substance:** other TS
**Source:** Union Camp Chemicals Durham
**Test substance:** Fatty acids, Tall oil is a mixture of naturally-occuring fatty acids (90% or more), rosin acids (up to 10% but usually less than 3.5%) and neutrals (unsaponafiables, 3.5% or less).
Toxicity data are given for the components of the mixture.
Record 2 = Linoleic acid

(1)

**Species:** rabbit
**Concentration:**

**Exposure:**
**Exposure Time:**
**Number of Animals:**
**PDII:**
**Result:** slightly irritating
**EC classificat.:**
**Method:**
**Year:** **GLP:** no data
**Test substance:** other TS
**Source:** Union Camp Chemicals Durham
**Test substance:** Fatty acids, Tall oil is a mixture of naturally-occuring fatty acids (90% or more), rosin acids (up to 10% but usually less than 3.5%) and neutrals (unsaponafiables, 3.5% or less).
Toxicity data are given for the components of the mixture.
Record 3 = Rosin acids

## 5.2.2 Eye Irritation

**Species:** rabbit
**Concentration:**
**Dose:**
**Exposure Time:**
**Comment:**
**Number of Animals:**
**Result:** slightly irritating
**EC classificat.:**
**Method:**
**Year:** **GLP:** no data
**Test substance:** other TS
**Source:** Union Camp Chemicals Durham
**Test substance:** Fatty acids, Tall oil is a mixture of naturally-occuring fatty acids (90% or more), rosin acids (up to 10% but usually less than 3.5%) and neutrals (unsaponafiables, 3.5% or less).
Toxicity data are given for the components of the mixture.
Record 1 = Oleic acid

(1)

**Species:** rabbit
**Concentration:**
**Dose:**
**Exposure Time:**
**Comment:**
**Number of Animals:**
**Result:** slightly irritating
**EC classificat.:**
**Method:**
**Year:** **GLP:** no data
**Test substance:** other TS

**Source:** Union Camp Chemicals Durham
**Test substance:** Fatty acids, Tall oil is a mixture of naturally-occuring fatty acids (90% or more), rosin acids (up to 10% but usually less than 3.5%) and neutrals (unsaponafiables, 3.5% or less).
Toxicity data are given for the components of the mixture.
Record 2 = Linoleic acid

(1)

## 5.3 Sensitization

**Type:**
**Species:**
**Number of Animals:**
**Vehicle:**
**Result:**
**Classification:**
**Method:**
**Year:** **GLP:**
**Test substance:**
**Remark:** A search of the literature via online databases such as the Hazardous Substances Databank and the Registry of Toxic Effects of Chemicals, which contain information on the various properties of chemical substances, revealed no data for this property.
**Source:** Union Camp Chemicals Durham

## 5.4 Repeated Dose Toxicity

**Species:** **Sex:**
**Strain:**
**Route of admin.:**
**Exposure period:**
**Frequency of treatment:**
**Post. obs. period:**
**Doses:**
**Control Group:**
**Method:**
**Year:** **GLP:**
**Test substance:**
**Remark:** A search of the literature via online databases such as the Hazardous Substances Databank and the Registry of Toxic Effects of Chemicals, which contain information on the various properties of chemical substances, revealed no data for this property.
**Source:** Union Camp Chemicals Durham

## 5.5 Genetic Toxicity 'in Vitro'

**Type:**
**System of testing:**
**Concentration:**
**Metabolic activation:**
**Result:**
**Method:**
**Year:** **GLP:**
**Test substance:**
**Remark:** A search of the literature via online databases such as the Hazardous Substances Databank and the Registry of Toxic Effects of Chemicals, which contain information on the various properties of chemical substances, revealed no data for this property.
**Source:** Union Camp Chemicals Durham

## 5.6 Genetic Toxicity 'in Vivo'

**Type:**
**Species:** **Sex:**
**Strain:**
**Route of admin.:**
**Exposure period:**
**Doses:**
**Result:**
**Method:**
**Year:** **GLP:**
**Test substance:**
**Remark:** A search of the literature via online databases such as the Hazardous Substances Databank and the Registry of Toxic Effects of Chemicals, which contain information on the various properties of chemical substances, revealed no data for this property.
**Source:** Union Camp Chemicals Durham

## 5.7 Carcinogenicity

**Species:** rabbit **Sex:**
**Strain:**
**Route of admin.:** s.c.
**Exposure period:**
**Frequency of treatment:**
**Post. obs. period:**
**Doses:**
**Result:**
**Control Group:**
**Method:**
**Year:** **GLP:** no data
**Test substance:** other TS
**Remark:** Available tumorigenic data for oleic acid is described as "questionable". Tumours were formed at the site of subcutaneous application.
**Result:** TDLO = 390 mg/kg/17 weeks.
**Source:** Union Camp Chemicals Durham
**Test substance:** Oleic acid, a component (up to 55%) of fatty acids, tall oil.

(1)

## 5.8 Toxicity to Reproduction

**Type:**
**Species:** **Sex:**
**Strain:**
**Route of admin.:**
**Exposure Period:**
**Frequency of treatment:**
**Duration of test:**
**Doses:**
**Control Group:**
**Method:**
**Year:** **GLP:**
**Test substance:**
**Remark:** A search of the literature via online databases such as the Hazardous Substances Databank and the Registry of Toxic Effects of Chemicals, which contain information on the various properties of chemical substances, revealed no data for this property.
**Source:** Union Camp Chemicals Durham

## 5.9 Developmental Toxicity/Teratogenicity

**Species:** **Sex:**
**Strain:**
**Route of admin.:**
**Exposure period:**
**Frequency of treatment:**
**Duration of test:**
**Doses:**
**Control Group:**
**Method:**
**Year:** **GLP:**
**Test substance:**
**Remark:** A search of the literature via online databases such as the Hazardous Substances Databank and the Registry of Toxic Effects of Chemicals, which contain information on the various properties of chemical substances, revealed no data for this property.
**Source:** Union Camp Chemicals Durham

## 5.10 Other Relevant Information

**Type:** other
**Remark:** A literature search of the TOXLINE database revealed a useful reference entitled, "Final report on the safety assessment of tall oil acid." An abstract follows:

Tall oil acid is a mixture of oleic, linoleic and rosin acids derived from the hydrolysis of tall oil, a by-product of wood pulp. Cosmetics formulated with tall oil acid include hair dyes abd bleaches, shampoos, skin cleansing preparations and a shaving cream. Tall oil acid is approved for use as an indirect food additive. When fed to rats as 15% of the total calorific intake, tall oil acid was non-toxic; however, it had a growth retarding effect. No treatment related effects were observed in rats fed diets containing 5% and 10% tall oil acid over two generations. Liquid soap formulations containing up to 12% tall oil acid did not cause dermal irritation, sensitization or photosensitization in human subjects. On the basis of data included in the report on tall oil acid and the available data on oleic acid, it is concluded that tall oil acid is safe for use in cosmetic products.
**Source:** Union Camp Chemicals Durham

(7)

## 5.11 Experience with Human Exposure

**Remark:** A search of the literature via online databases such as the Hazardous Substances Databank and the Registry of Toxic Effects of Chemicals, which contain information on the various properties of chemical substances, revealed no data for this property.
**Source:** Union Camp Chemicals Durham

(1) Unknown.

(2) Study report:Determination of partition coefficient.
Performed at:SafePharm Laboratories Ltd.
P.O. Box No. 45
Derby DE1 2BT
U.K.
Study Director:D Mullee
Project No.: 508/32
Date:March 1994

(3) Study report:Assessment of the Ready Biodegradability of Unitol BKS using the CO2 evolution test (modified sturm test)
Performed at:SafePharm Laboratories Ltd.
P.O. Box No. 45
Derby DE1 2BT
U.K.
Study Director:I Sewell
Project No.: 508/28
Date: March 1994

(4) Study report:The acute toxicity of Unitol BKS to Golden Orfe
Performed at:SafePharm Laboratories Ltd.
P.O. Box No. 45
Derby DE1 2BT
U.K.
Study Director:I Sewell
Project No.: 508/29
Date:March 1994

(5) Study report:The acute toxicity of Unitol BKS to Daphnia magna
Performed at:SafePharm Laboratories Ltd.
P.O. Box No. 45
Derby DE1 2BT
U.K.
Study Director: I Sewell
Project No.: 508/30
Date: March 1994

(6) Study report:Assessment of the algistatic effect of Unitol BKS.
Performed at:SafePharm Laboratories Ltd.
P.O. Box No. 45
Derby DE1 2BT
U.K.
Study Director:I Sewell
Project No.: 508/31¿
Date: March 1994

(7) Author: anonymous
Source:J-Am-Coll-Toxicol 8 (4) : 769-76
Year: 1989
ISSN: 0730-0913

## 7.1 Risk Assessment

-

# IUCLID

# Data Set

| | | |
|---|---|---|
| **Existing Chemical** | : | ID: 57-11-4 |
| **EINECS Name** | : | stearic acid |
| **EC No.** | : | 200-313-4 |
| **Molecular Formula** | : | C18H36O2 |

**Producer related part**

| | | |
|---|---|---|
| **Company** | : | Epona Associates, LLC |
| **Creation date** | : | 04.12.2003 |

**Substance related part**

| | | |
|---|---|---|
| **Company** | : | Epona Associates, LLC |
| **Creation date** | : | 04.12.2003 |
| **Status** | : | |
| **Memo** | : | SOCMA MCC |
| **Printing date** | : | 05.12.2003 |
| **Revision date** | : | |
| **Date of last update** | : | 05.12.2003 |
| **Number of pages** | : | 22 |
| **Chapter (profile)** | : | Chapter: 1, 2, 3, 4, 5, 6, 7, 8, 10 |
| **Reliability (profile)** | : | Reliability: without reliability, 1, 2, 3, 4 |
| **Flags (profile)** | : | Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE), Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS |

### 1.0.1 APPLICANT AND COMPANY INFORMATION

### 1.0.2 LOCATION OF PRODUCTION SITE, IMPORTER OR FORMULATOR

### 1.0.3 IDENTITY OF RECIPIENTS

### 1.0.4 DETAILS ON CATEGORY/TEMPLATE

### 1.1.0 SUBSTANCE IDENTIFICATION

### 1.1.1 GENERAL SUBSTANCE INFORMATION

| | | |
|---|---|---|
| **Purity type** | : | |
| **Substance type** | : | organic |
| **Physical status** | : | solid |
| **Purity** | : | |
| **Colour** | : | Colorless, waxy solid |
| **Odour** | : | SLIGHT TALLOW-LIKE ODOR |
| **Source** | : | Epona Associates, LLC |
| **Reliability** | : | (2) valid with restrictions<br>Information taken from a peer-reviewed publication. |

04.12.2003 (5)

04.12.2003

### 1.1.2 SPECTRA

### 1.2 SYNONYMS AND TRADENAMES

### 1.3 IMPURITIES

### 1.4 ADDITIVES

### 1.5 TOTAL QUANTITY

### 1.6.1 LABELLING

### 1.6.2 CLASSIFICATION

### 1.6.3 PACKAGING

### 1.7 USE PATTERN

### 1.7.1 DETAILED USE PATTERN

### 1.7.2 METHODS OF MANUFACTURE

### 1.8 REGULATORY MEASURES

**Type of measure** :
**Legal basis** : other: Generally Recognized as Safe

**Remark** : [Code of Federal Regulations]
[Title 21, Volume 3]
[Revised as of April 1, 2003]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR184.1090]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
PART 184--DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

Subpart B--Listing of Specific Substances Affirmed as GRAS

Sec. 184.1090 Stearic acid.

(a) Stearic acid (C16H36O2, CAS Reg. No. 57-11-4) is a white to yellowish white solid. It occurs naturally as a glyceride in tallow and other animal or vegetable fats and oils and is a principal constituent of most commercially hydrogenated fats. It is produced commercially from hydrolyzed tallow derived from edible sources or from hydrolyzed, completely hydrogenated vegetable oil derived from edible sources.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 313, which is incorporated by reference, and the requirements of Sec. 172.860(b)(2) of this chapter. Copies of the Food Chemicals Codex are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with Sec. 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as

defined in Sec. 170.3(o)(12) of this chapter.
(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.
(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52445, Nov. 18, 1983, as amended at 50 FR 49536, Dec. 3, 1985]

**Reliability** : (1) valid without restriction
05.12.2003

**1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES**

**1.8.2 ACCEPTABLE RESIDUES LEVELS**

**1.8.3 WATER POLLUTION**

**1.8.4 MAJOR ACCIDENT HAZARDS**

**1.8.5 AIR POLLUTION**

**1.8.6 LISTINGS E.G. CHEMICAL INVENTORIES**

**1.9.1 DEGRADATION/TRANSFORMATION PRODUCTS**

**1.9.2 COMPONENTS**

**1.10 SOURCE OF EXPOSURE**

**1.11 ADDITIONAL REMARKS**

**1.12 LAST LITERATURE SEARCH**

**1.13 REVIEWS**

### 2.1 MELTING POINT

| | | |
|---|---|---|
| **Value** | : | = 69 - 70 °C |
| **Sublimation** | : | |
| **Method** | : | |
| **Year** | : | 1982 |
| **GLP** | : | no data |
| **Test substance** | : | as prescribed by 1.1 - 1.4 |
| **Source** | : | Epona Associates, LLC |
| **Reliability** | : | (2) valid with restrictions<br>Information taken from a peer-reviewed publication. |
| **Flag** | : | Critical study for SIDS endpoint |

04.12.2003 (16)

### 2.2 BOILING POINT

| | | |
|---|---|---|
| **Value** | : | = 383 °C at 1013 hPa |
| **Decomposition** | : | |
| **Method** | : | |
| **Year** | : | |
| **GLP** | : | no data |
| **Test substance** | : | as prescribed by 1.1 - 1.4 |
| **Source** | : | Epona Associates, LLC |
| **Reliability** | : | (2) valid with restrictions<br>Information taken from a peer-reviewed publication. |
| **Flag** | : | Critical study for SIDS endpoint |

04.12.2003 (16)

### 2.3 DENSITY

#### 2.3.1 GRANULOMETRY

### 2.4 VAPOUR PRESSURE

| | | |
|---|---|---|
| **Value** | : | = 1.33 hPa at 173.7 °C |
| **Decomposition** | : | |
| **Method** | : | |
| **Year** | : | 1969 |
| **GLP** | : | no data |
| **Test substance** | : | as prescribed by 1.1 - 1.4 |
| **Source** | : | Epona Associates, LLC |
| **Reliability** | : | (2) valid with restrictions<br>Information taken from a peer-reviewed publication. |
| **Flag** | : | Critical study for SIDS endpoint |

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### 2.5 PARTITION COEFFICIENT

| | | |
|---|---|---|
| **Partition coefficient** | : | octanol-water |
| **Log pow** | : | = 8.42 at °C |
| **pH value** | : | |
| **Method** | : | |
| **Year** | : | |
| **GLP** | : | no data |
| **Test substance** | : | as prescribed by 1.1 - 1.4 |
| **Source** | : | Epona Associates, LLC |
| **Reliability** | : | (2) valid with restrictions<br>Information taken from a peer-reviewed publication. |

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### 2.6.1 SOLUBILITY IN DIFFERENT MEDIA

| | | |
|---|---|---|
| **Solubility in** | : | Water |
| **Value** | : | = .568 mg/l at 25 °C |
| **pH value** | : | |
| **concentration** | : | at °C |
| **Temperature effects** | : | |
| **Examine different pol.** | : | |
| **pKa** | : | at 25 °C |
| **Description** | : | |
| **Stable** | : | |
| **Deg. product** | : | |
| **Method** | : | other: measured |
| **Year** | : | 1966 |
| **GLP** | : | no data |
| **Test substance** | : | as prescribed by 1.1 - 1.4 |
| **Result** | : | Water solubility = .0001 mg/L at 30 deg C |
| **Reliability** | : | (2) valid with restrictions<br>Information taken from a peer-reviewed publication. |

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### 2.6.2 SURFACE TENSION

### 2.7 FLASH POINT

### 2.8 AUTO FLAMMABILITY

### 2.9 FLAMMABILITY

### 2.10 EXPLOSIVE PROPERTIES

### 2.11 OXIDIZING PROPERTIES

### 2.12 DISSOCIATION CONSTANT

## 2.13 VISCOSITY

## 2.14 ADDITIONAL REMARKS

### 3.1.1 PHOTODEGRADATION

| | | |
|---|---|---|
| **Type** | : | air |
| **Light source** | : | |
| **Light spectrum** | : | nm |
| **Relative intensity** | : | based on intensity of sunlight |
| **DIRECT PHOTOLYSIS** | | |
| **Halflife t1/2** | : | = .5 day(s) |
| **Degradation** | : | % after |
| **Quantum yield** | : | |
| **Deg. product** | : | |
| **Method** | : | other (calculated) |
| **Year** | : | 2003 |
| **GLP** | : | no |
| **Test substance** | : | as prescribed by 1.1 - 1.4 |
| **Method** | : | Estimated using AopWin v1.91 |
| **Result** | : | Atmospheric Oxidation (25 deg C) [AopWin v1.91]:<br>Hydroxyl Radicals Reaction:<br>OVERALL OH Rate Constant = 22.4804 E-12 cm3/molecule-sec<br>Half-Life = 0.476 Days (12-hr day; 1.5E6 OH/cm3)<br>Half-Life = 5.710 Hrs<br>Ozone Reaction:<br>No Ozone Reaction Estimation |
| **Source** | : | Epona Associates, LLC |
| **Reliability** | : | (2) valid with restrictions |
| **Flag** | : | Critical study for SIDS endpoint |

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| | | |
|---|---|---|
| **Type** | : | air |
| **Light source** | : | |
| **Light spectrum** | : | nm |
| **Relative intensity** | : | based on intensity of sunlight |
| **DIRECT PHOTOLYSIS** | | |
| **Halflife t1/2** | : | = 17 hour(s) |
| **Degradation** | : | % after |
| **Quantum yield** | : | |
| **Deg. product** | : | |
| **Method** | : | |
| **Year** | : | |
| **GLP** | : | no data |
| **Test substance** | : | as prescribed by 1.1 - 1.4 |
| **Result** | : | Vapor phase stearic acid is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals with a half-life of about 17 hours. |
| **Source** | : | Epona Associates, LLC |
| **Reliability** | : | (2) valid with restrictions<br>Information taken from a peer-reviewed publication. |

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### 3.1.2 STABILITY IN WATER

### 3.1.3 STABILITY IN SOIL

### 3.2.1 MONITORING DATA

### 3.2.2 FIELD STUDIES

### 3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

| | | |
|---|---|---|
| **Type** | : | fugacity model level III |
| **Media** | : | |
| **Air** | : | % (Fugacity Model Level I) |
| **Water** | : | % (Fugacity Model Level I) |
| **Soil** | : | % (Fugacity Model Level I) |
| **Biota** | : | % (Fugacity Model Level II/III) |
| **Soil** | : | % (Fugacity Model Level II/III) |
| **Method** | : | other: modeling |
| **Year** | : | 2003 |
| **Method** | : | EPI v3.11 |
| **Result** | : | Level III Fugacity Model:<br>Mass Amount Half-Life Emissions<br>(percent) (hr) (kg/hr)<br>Air 0.676 11.4 1000<br>Water 7.19 360 1000<br>Soil 28.9 360 1000<br>Sediment 63.3 1.44e+003 0<br>Persistence Time: 640 hr |
| **Source** | : | Epona Associates, LLC |
| **Reliability** | : | (2) valid with restrictions |
| **Flag** | : | Critical study for SIDS endpoint |

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### 3.3.2 DISTRIBUTION

### 3.4 MODE OF DEGRADATION IN ACTUAL USE

### 3.5 BIODEGRADATION

| | | |
|---|---|---|
| **Type** | : | aerobic |
| **Inoculum** | : | activated sludge |
| **Contact time** | : | |
| **Degradation** | : | = 77 (±) % after 28 day(s) |
| **Result** | : | readily biodegradable |
| **Kinetic of testsubst.** | : | 10 day(s) = 65 %<br>14 day(s) = 69 %<br>28 day(s) = 77 %<br>%<br>% |
| **Deg. product** | : | |
| **Method** | : | other: BOD test |
| **Year** | : | 1983 |
| **GLP** | : | no data |
| **Test substance** | : | as prescribed by 1.1 - 1.4 |
| **Remark** | : | Results are an average of 11 participating laboratories. |

| | | |
|---|---|---|
| **Result** | : | 65, 69 and 77 % degradation after 10, 14 and 28 days, respectively. |
| **Source** | : | Epona Associates, LLC |
| **Reliability** | : | (2) valid with restrictions<br>Information taken from a peer-reviewed publication. |

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| | | |
|---|---|---|
| **Type** | : | aerobic |
| **Inoculum** | : | activated sludge |
| **Concentration** | : | 100 g/l related to Test substance<br>related to |
| **Contact time** | : | 5 day(s) |
| **Degradation** | : | (±) % after |
| **Result** | : | readily biodegradable |
| **Deg. product** | : | |
| **Method** | : | other: BOD5 |
| **Year** | : | 1985 |
| **GLP** | : | no data |
| **Test substance** | : | as prescribed by 1.1 - 1.4 |
| **Result** | : | Rate: .0088 1/HR<br><br>Half-Life [Days]: 3.3 |
| **Source** | : | Epona Associates, LLC |
| **Test condition** | : | BOD test conducted at 20 deg C. |
| **Reliability** | : | (2) valid with restrictions<br>Information taken from a peer-reviewed publication. |

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| | | |
|---|---|---|
| **Type** | : | aerobic |
| **Inoculum** | : | other: sewage sludge |
| **Contact time** | : | 21 day(s) |
| **Degradation** | : | = 95 (±) % after 21 day(s) |
| **Result** | : | readily biodegradable |
| **Deg. product** | : | |
| **Method** | : | other: Sturm $CO_2$ evolution |
| **Year** | : | 1984 |
| **GLP** | : | no data |
| **Test substance** | : | as prescribed by 1.1 - 1.4 |
| **Source** | : | Epona Associates, LLC |
| **Reliability** | : | (2) valid with restrictions<br>Information taken from a peer-reviewed publication. |
| **Flag** | : | Critical study for SIDS endpoint |

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| | | |
|---|---|---|
| **Type** | : | aerobic |
| **Inoculum** | : | activated sludge |
| **Contact time** | : | |
| **Degradation** | : | (±) % after |
| **Result** | : | readily biodegradable |
| **Deg. product** | : | |
| **Method** | : | other: Warburg |
| **Year** | : | 1973 |
| **GLP** | : | no data |
| **Test substance** | : | as prescribed by 1.1 - 1.4 |
| **Result** | : | Rate: .0077; .0052; .00217<br><br>Rate Units: 1/HR<br><br>Half-Life [Days]: 3.75; 5.55; 10.7 |
| **Source** | : | Epona Associates, LLC |

**Test condition** : Test Method: WARBURG

Oxygen Condition: AEROBIC

Analysis Method: 02 UPTAKE

Inoculum: ACTIVATED SLUDGE

Temperature [øC]: 20; 25; 30

**Reliability** : (2) valid with restrictions
Information taken from a peer-reviewed publication.

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## 3.6 BOD5, COD OR BOD5/COD RATIO

## 3.7 BIOACCUMULATION

## 3.8 ADDITIONAL REMARKS

## 4.1 ACUTE/PROLONGED TOXICITY TO FISH

| | | |
|---|---|---|
| **Type** | : | static |
| **Species** | : | Oncorhynchus kisutch (Fish, fresh water, marine) |
| **Exposure period** | : | > 96 hour(s) |
| **Unit** | : | µg/l |
| **LC50** | : | = 12000 measured/nominal |
| **Method** | : | The test result is actually LT50 not LC50 |
| **Year** | : | 1977 |
| **GLP** | : | no data |
| **Test substance** | : | as prescribed by 1.1 - 1.4 |
| **Source** | : | Epona Associates, LLC |
| **Test substance** | : | "pure" |
| **Reliability** | : | (2) valid with restrictions |
| **Flag** | : | Critical study for SIDS endpoint |

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## 4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

## 4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

## 4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

## 4.5.1 CHRONIC TOXICITY TO FISH

## 4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

## 4.6.1 TOXICITY TO SEDIMENT DWELLING ORGANISMS

## 4.6.2 TOXICITY TO TERRESTRIAL PLANTS

## 4.6.3 TOXICITY TO SOIL DWELLING ORGANISMS

## 4.6.4 TOX. TO OTHER NON MAMM. TERR. SPECIES

## 4.7 BIOLOGICAL EFFECTS MONITORING

## 4.8 BIOTRANSFORMATION AND KINETICS

### 4.9 ADDITIONAL REMARKS

## 5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

### 5.1.1 ACUTE ORAL TOXICITY

| | | |
|---|---|---|
| **Type** | : | LD50 |
| **Value** | : | = 4600 mg/kg bw |
| **Species** | : | rat |
| **Strain** | : | |
| **Sex** | : | |
| **Number of animals** | : | |
| **Vehicle** | : | |
| **Doses** | : | |
| **Method** | : | |
| **Year** | : | |
| **GLP** | : | no data |
| **Test substance** | : | as prescribed by 1.1 - 1.4 |
| **Source** | : | Epona Associates, LLC |
| **Reliability** | : | (2) valid with restrictions<br>Information taken from a peer-reviewed publication. |

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| | | |
|---|---|---|
| **Type** | : | LD100 |
| **Value** | : | = 14286 - mg/kg bw |
| **Species** | : | human |
| **Strain** | : | |
| **Sex** | : | |
| **Number of animals** | : | |
| **Vehicle** | : | |
| **Doses** | : | |
| **Method** | : | |
| **Year** | : | 1976 |
| **GLP** | : | no data |
| **Test substance** | : | as prescribed by 1.1 - 1.4 |
| **Result** | : | Minimum/Potential Fatal Human Dose:<br>1. 1= PRACTICALLY NONTOXIC: PROBABLE ORAL LETHAL DOSE (HUMAN) MORE THAN 1<br>QT (2.2 LB) FOR 70 KG PERSON (150 LB). |
| **Source** | : | Epona Associates, LLC |
| **Reliability** | : | (2) valid with restrictions<br>Information taken from a peer-reviewed publication. |

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### 5.1.2 ACUTE INHALATION TOXICITY

### 5.1.3 ACUTE DERMAL TOXICITY

### 5.1.4 ACUTE TOXICITY, OTHER ROUTES

### 5.2.1 SKIN IRRITATION

### 5.2.2 EYE IRRITATION

### 5.3 SENSITIZATION

### 5.4 REPEATED DOSE TOXICITY

| | | |
|---|---|---|
| **Type** | : | Sub-chronic |
| **Species** | : | rat |
| **Sex** | : | |
| **Strain** | : | |
| **Route of admin.** | : | oral feed |
| **Exposure period** | : | 24 weeks |
| **Frequency of treatm.** | : | |
| **Post exposure period** | : | |
| **Doses** | : | 50g/kg/day |
| **Control group** | : | |
| **Method** | : | |
| **Year** | : | |
| **GLP** | : | no data |
| **Test substance** | : | as prescribed by 1.1 - 1.4 |
| **Result** | : | Rats fed 50 g/kg/day stearic acid for 24 weeks developed reversible lipogranulomas in adipose tissue. No significant pathological lesions were observed in rats fed 3000 ppm stearic acid orally for about 30 weeks, but anorexia, increased mortality, and a greater incidence of pulmonary infection were observed. Stearic acid is one of the least effective fatty acids in producing hyperlipemia, but the most potent in diminishing blood clotting time. |
| **Source** | : | Epona Associates, LLC |
| **Reliability** | : | (2) valid with restrictions<br>Information taken from a peer-reviewed publication. |

05.12.2003 (2)

| | | |
|---|---|---|
| **Type** | : | Sub-acute |
| **Species** | : | rat |
| **Sex** | : | |
| **Strain** | : | |
| **Route of admin.** | : | oral feed |
| **Exposure period** | : | 6 or 9 weeks |
| **Frequency of treatm.** | : | |
| **Post exposure period** | : | |
| **Doses** | : | 5 or 6% |
| **Control group** | : | |
| **Result** | : | Rats fed 5% stearic acid as part of a high-fat diet for 6 weeks, or 6% stearic acid for 9 weeks, showed a decreased blood clotting time and hyperlipemia. |
| **Source** | : | Epona Associates, LLC |
| **Reliability** | : | (2) valid with restrictions<br>Information taken from a peer-reviewed publication. |

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| | | |
|---|---|---|
| **Type** | : | Sub-acute |
| **Species** | : | mouse |

| | | |
|---|---|---|
| **Sex** | : | |
| **Strain** | : | |
| **Route of admin.** | : | oral feed |
| **Exposure period** | : | 3 weeks |
| **Frequency of treatm.** | : | |
| **Post exposure period** | : | |
| **Doses** | : | 5 to 50% |
| **Control group** | : | |
| **Method** | : | |
| **Year** | : | |
| **GLP** | : | no data |
| **Test substance** | : | as prescribed by 1.1 - 1.4 |
| **Result** | : | When diets containing 5 to 50% stearic acid (as the monoglyceride) were fed to weanling mice for 3 weeks, depression of weight gain was seen above the 10% dietary level. Mortality occurred only with the 50% diet. The effects were less noticeable in adult mice. |
| **Source** | : | Epona Associates, LLC |
| **Reliability** | : | (2) valid with restrictions<br>Information taken from a peer-reviewed publication. |

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## 5.5 GENETIC TOXICITY 'IN VITRO'

## 5.6 GENETIC TOXICITY 'IN VIVO'

## 5.7 CARCINOGENICITY

## 5.8.1 TOXICITY TO FERTILITY

## 5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

## 5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES

## 5.9 SPECIFIC INVESTIGATIONS

## 5.10 EXPOSURE EXPERIENCE

## 5.11 ADDITIONAL REMARKS

## 6.1 ANALYTICAL METHODS

## 6.2 DETECTION AND IDENTIFICATION

## 7.1 FUNCTION

## 7.2 EFFECTS ON ORGANISMS TO BE CONTROLLED

## 7.3 ORGANISMS TO BE PROTECTED

## 7.4 USER

## 7.5 RESISTANCE

## 8.1 METHODS HANDLING AND STORING

## 8.2 FIRE GUIDANCE

## 8.3 EMERGENCY MEASURES

## 8.4 POSSIB. OF RENDERING SUBST. HARMLESS

## 8.5 WASTE MANAGEMENT

## 8.6 SIDE-EFFECTS DETECTION

## 8.7 SUBSTANCE REGISTERED AS DANGEROUS FOR GROUND WATER

## 8.8 REACTIVITY TOWARDS CONTAINER MATERIAL

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## 10.1 END POINT SUMMARY

## 10.2 HAZARD SUMMARY

## 10.3 RISK ASSESSMENT